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The MiniMed 780G automated insulin delivery system adapts to substantial changes in daily routine: Lessons from real world users during Ramadan

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Abstract

Aim: To report on the effectiveness and safety of the MiniMed 780G automated insulin delivery system in real-world users during the month of Ramadan.

Materials and Methods: CareLink Personal data were extracted from MiniMed 780G system users from the Gulf region. Users were included if they had ≥ 10 days of sensor glucose data during the month of Ramadan 2022 as well as in the month before and after. For the main analysis, continuous glucose monitoring endpoints were aggregated per month and were reported by time of day (daytime: 05.31-18.00 h,

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and night-time). Additional analyses were performed to study the pace at which the algorithm adapts.

Results: Glycaemic control was well kept in the 449 included users (mean sensor glucose = 152.6 ± 18.7 mg/dl, glucose management indicator = $7.0 \pm 0.4\%$, time in range = $70.7 \pm 11.0\%$, time below 70 mg/dl = $2.3 \pm 2.3\%$). Albeit some metrics differed from the month before ($p < .0001$ for all), absolute differences were very small and considered clinically irrelevant. During Ramadan, there was no increased risk of hypoglycaemia during daytime (time below 70 mg/dl = $2.3 \pm 2.4\%$), time in range was highest during daytime ($80.0 \pm 10.7\%$, night: $60.4 \pm 15.3\%$), while time above 180 mg/dl was highest during night-time ($37.3 \pm 16.3\%$, day: $17.7 \pm 10.7\%$). The algorithm adapted immediately upon lifestyle change.

Conclusion: The MiniMed 780G automated insulin delivery system is effective, safe and fast in adapting to the substantial changes that occur in the lifestyle of people with type 1 diabetes during Ramadan.

KEYWORDS

type 1 diabetes, real-world evidence, insulin therapy, continuous glucose monitoring (CGM)

1 | INTRODUCTION

The rapid advancement of automated insulin delivery (AID) systems has revolutionized glycaemic control outcomes for people with type 1 diabetes (PwT1D). These systems, now incorporated into international guidelines for T1D treatment, have shown remarkable efficacy in both adult and paediatric populations.^{1–3} The MiniMed 780G AID system was introduced for clinical use in 2020, and includes the so-called Advanced Hybrid Closed Loop algorithm. This algorithm automatically administers basal insulin and autocorrection boluses every 5 min (as needed), aiming to maintain a predefined glucose target (GT). Extensive clinical trials and real-world analyses have confirmed the MiniMed 780G system's ability to exceed recommended international glycaemic targets safely.^{4–7}

During the holy month of Ramadan, individuals who observe fasting as well as their families, experience significant changes in their daily routines. These changes encompass not only dietary habits but also disruption in exercise, sleep patterns and overall lifestyle. Fasting during Ramadan poses a heightened risk of acute complications for PwT1D, including hypoglycaemia, hyperglycaemia, dehydration and diabetic ketoacidosis, particularly during the fasting hours spanning from the Fajr (dawn) prayer to the Maghrib prayer (just after sunset). Although PwT1D are exempt from fasting for medical reasons, many opt to observe to the fast (or otherwise change their lifestyle during this period).⁸ Both the International Diabetes Federation (IDF) and Diabetes and Ramadan International Alliance (DAR) have developed guidelines that risk stratify patients to offer appropriate guidance to PwT1D who choose to fast during Ramadan; these guidelines aim to assist both fasting PwT1D and their health care professionals.⁹ However, the current version of the guidelines has not yet incorporated AID systems into the risk assessment.

The MiniMed 780G system has shown efficacy and safety during the month of Ramadan in a randomized controlled trial¹⁰ and in a case

report.¹¹ Both studies, however, were conducted in highly controlled settings and for a proper performance and safety profile of the MiniMed 780G system during Ramadan unbiased real-world evidence is needed. Here, we report on the effectiveness and safety of the MiniMed 780G AID system in real-world users during the month of Ramadan.

2 | MATERIALS AND METHODS

2.1 | Design

This is a retrospective observational study based on real-world data as collected in CareLink Personal, conducted in the Gulf region (i.e. Kingdom of Saudi Arabia, Qatar, United Arab Emirates, Bahrain, Kuwait, Oman, Yemen). The endpoints were continuous glucose monitoring (CGM)-based metrics, such as metrics of glycaemic control (based on the 'recommendations from the international consensus on time in range'),¹² system characteristics and metrics of insulin use. The full list of endpoints is included in Table 1.

2.2 | Data source

CareLink Personal is a software program that collects information directly from MiniMed systems, and users can generate reports and monitor progress. In terms of data representativity, CareLink Personal contains data from all users that have created a CareLink Personal account. In the Gulf region, PwT1D starting on the MiniMed 780G system undergo device training either in-person or virtually (by certified product trainers or by Medtronic personnel), and the creation of a CareLink Personal account is part of the training module. The conservative

TABLE 1 Continuous glucose monitoring based metrics in the main cohort during Ramadan, and in the month before and after.

	Ramadan	Before	After	Change during-before (95% CI), <i>p</i> value	Change during-after (95% CI), <i>p</i> value
General					
N	449				
Age groups, years; <i>n</i> (%)					
≤15	247 (55.0)				
>15	202 (45.0)				
Gender, <i>n</i> (%)					
Female	245 (54.6)				
Male	204 (45.4)				
System time, days	28.2 ± 3.3	27.7 ± 5.1	29.2 ± 3.3		
Glycaemic control					
Sensor glucose, mg/dl	152.6 ± 18.7	150.3 ± 18.4	152.6 ± 18.3	2.4 (1.3 to 3.4), <i>p</i> < .0001	−0.0 (−0.9 to 0.9), <i>p</i> = .5653
SD of SG, mg/dl	54.8 ± 12.2	53.6 ± 11.9	54.2 ± 11.3	1.2 (0.7 to 1.8), <i>p</i> < .0001	0.6 (0.1 to 1.2), <i>p</i> = .1983
Glucose management indicator, %	7.0 ± 0.4	6.9 ± 0.4	7.0 ± 0.4	0.1 (0.0 to 0.1), <i>p</i> < .0001	−0.0 (−0.0 to 0.0), <i>p</i> = .5653
Time in range, % of time					
Time below 54 mg/dl	0.5 ± 0.7	0.6 ± 0.9	0.6 ± 0.9	−0.1 (−0.2 to −0.1), <i>p</i> < .0001	−0.1 (−0.1 to −0.0), <i>p</i> = .0046
Time below 70 mg/dl	2.3 ± 2.3	2.6 ± 2.5	2.4 ± 2.4	−0.4 (−0.5 to −0.2), <i>p</i> < .0001	−0.1 (−0.3 to −0.0), <i>p</i> = .0103
Time between 70 and 180 mg/dl	70.7 ± 11.0	71.7 ± 11.0	70.5 ± 10.8	−1.1 (−1.7 to −0.5), <i>p</i> < .0001	0.1 (−0.5 to 0.7), <i>p</i> = .2018
Time above 180 mg/dl	27.1 ± 11.6	25.7 ± 11.6	27.0 ± 11.5	1.4 (0.8 to 2.1), <i>p</i> < .0001	0.0 (−0.5 to 0.6), <i>p</i> = .5766
Time above 250 mg/dl	7.1 ± 6.2	6.3 ± 5.8	6.7 ± 5.9	0.8 (0.5 to 1.1), <i>p</i> < .0001	0.3 (0.0 to 0.7), <i>p</i> = .1331
Users reaching targets, % of users					
TIR >70%	53.0	56.6	52.6		
TB70 <4%	84.0	80.6	83.5		
GMI <7%	54.6	61.2	54.6		
Glycaemic control during daytime (05.31-18.00 h)					
Time below 54 mg/dl, %	0.5 ± 0.8	0.6 ± 0.9	0.6 ± 0.9	−0.1 (−0.2 to −0.0), <i>p</i> = .0044	−0.1 (−0.2 to −0.0), <i>p</i> = .0091
Time below 70 mg/dl, %	2.3 ± 2.4	2.6 ± 2.5	2.4 ± 2.5	−0.3 (−0.5 to −0.1), <i>p</i> = .0022	−0.1 (−0.3 to 0.0), <i>p</i> = .0220
Time between 70 and 180 mg/dl, %	80.0 ± 10.7	74.7 ± 11.5	73.9 ± 11.1	5.3 (4.4 to 6.1), <i>p</i> < .0001	6.1 (5.3 to 6.9), <i>p</i> < .0001
Time above 180 mg/dl, %	17.7 ± 10.7	22.7 ± 11.8	23.7 ± 11.5	−5.0 (−5.8 to −4.1), <i>p</i> < .0001	−6.0 (−6.8 to −5.2), <i>p</i> < .0001
Time above 250 mg/dl, %	4.0 ± 5.0	5.5 ± 5.8	5.9 ± 5.7	−1.5 (−1.9 to −1.1), <i>p</i> < .0001	−1.9 (−2.3 to −1.5), <i>p</i> < .0001
Manual boluses, <i>n</i> /d	1.5 ± 1.5	3.0 ± 1.5	2.8 ± 1.5		
Glycaemic control during night-time (18.01-05.30 h)					
Time below 54 mg/dl, %	0.5 ± 0.8	0.7 ± 1.0	0.6 ± 0.9	−0.1 (−0.2 to −0.1), <i>p</i> < .0001	−0.1 (−0.1 to −0.0), <i>p</i> = .0308
Time below 70 mg/dl, %	2.3 ± 2.6	2.7 ± 2.8	2.4 ± 2.6	−0.4 (−0.6 to −0.3), <i>p</i> < .0001	−0.2 (−0.3 to −0.0), <i>p</i> = .0084

(Continues)

TABLE 1 (Continued)

	Ramadan	Before	After	Change during-before (95% CI), <i>p</i> value	Change during-after (95% CI), <i>p</i> value
Time between 70 and 180 mg/dl, %	60.4 ± 15.3	68.3 ± 12.4	67.0 ± 12.6	−7.8 (−8.8 to −6.9), <i>p</i> < .0001	−6.6 (−7.4 to −5.7), <i>p</i> < .0001
Time above 180 mg/dl, %	37.3 ± 16.3	29.0 ± 13.2	30.6 ± 13.5	8.3 (7.3 to 9.3), <i>p</i> < .0001	6.7 (5.8 to 7.6), <i>p</i> < .0001
Time above 250 mg/dl, %	10.4 ± 9.0	7.1 ± 6.6	7.5 ± 6.8	3.3 (2.7 to 3.8), <i>p</i> < .0001	2.8 (2.3 to 3.4), <i>p</i> < .0001
Manual boluses, n/d	3.5 ± 1.6	2.3 ± 1.2	2.4 ± 1.2		
System characteristics					
Time in automation, %	92.6 ± 14.1	92.2 ± 14.8	90.6 ± 16.8		
Automation exits, n/w	1.2 ± 1.4	1.1 ± 1.1	1.1 ± 1.3		
SMBGs per day, n/d	3.0 ± 1.3	3.0 ± 1.3	3.0 ± 1.3		
Alarms per day, n/d	10.9 ± 5.8	11.1 ± 6.0	11.0 ± 5.9		
Glucose target, % of time					
100 mg/dl	41.6 ± 45.3	48.1 ± 46.6	45.4 ± 46.5		
110 mg/dl	23.0 ± 38.7	22.7 ± 39.1	23.5 ± 40.0		
120 mg/dl	26.3 ± 40.4	24.0 ± 40.0	25.2 ± 40.5		
150 mg/dl	4.2 ± 10.2	0.8 ± 3.1	1.3 ± 4.1		
Users with >95% in GT, % of users					
100 mg/dl	25.4	35.2	30.5		
110 mg/dl	12.5	15.1	15.4		
120 mg/dl	14.0	15.1	15.1		
Active insulin time, % of time					
2 h	24.8 ± 42.7	24.0 ± 42.1	26.3 ± 43.3		
2-3 h	63.3 ± 47.4	62.6 ± 47.2	62.4 ± 47.5		
3-4 h	11.5 ± 31.2	12.9 ± 32.3	10.9 ± 30.2		
>4 h	0.4 ± 5.6	0.4 ± 6.6	0.4 ± 5.4		
Users with >95% in AIT, % of users					
2 h	23.6	22.5	24.5		
2-3 h	61.0	59.2	60.4		
3-4 h	10.5	10.5	9.4		
>4 h	0.2	0.4	0.2		
Insulin					
Carbohydrates, g/day	168.4 ± 73.3	174.2 ± 75.5	176.0 ± 81.0		
Insulin to carbs, ratio	10.9 ± 6.3	11.0 ± 6.4	10.7 ± 6.2	−0.15 (−0.3 to −0.1), <i>p</i> = .01200	0.16 (0.1 to 0.2), <i>p</i> = <0.0001
Total daily insulin dose, U/day	45.2 ± 25.1	45.8 ± 25.6	47.6 ± 26.4	−0.6 (−1.3 to 0.1), <i>p</i> = .11411	−2.4 (−3.1 to −1.7), <i>p</i> < .0001
Insulin delivery, % of TDD					
Automatically	56.3 ± 12.1	55.7 ± 11.9	56.2 ± 12.2		
Autobasal	40.9 ± 7.7	40.6 ± 7.8	40.6 ± 7.9		
Autocorrection bolus	15.4 ± 7.1	15.0 ± 7.1	15.6 ± 7.4		
Manual bolus	43.7 ± 12.1	44.3 ± 11.9	43.8 ± 12.2		
Manual boluses, n/d	5.0 ± 2.3	5.3 ± 2.3	5.3 ± 2.5		

Note: Values are presented as means ± SD.

Abbreviations: 95% CI, 95% confidence interval; AIT, active insulin time; GMI, glucose management indicator; GT, glucose target; n/d, number per day; n/w, number per week; SG, sensor glucose; SMBG, self-monitoring blood glucose; TB70, time below 70 mg/dl; TDD, total daily dose; TIR, time in range.

estimate is that at least 90% of the Gulf region MiniMed 780G system users have a CareLink Personal account. The majority of users (97%) have consented for their data to be used (anonymized for research purposes). The Gulf region was chosen as a location for the study as over 70% of the population in this region is Muslim (Ramadan is one of the five pillars of Islam and one of the holiest months for Muslims). In the Gulf region, Ramadan is observed at a regional level.¹³

In terms of data quality, pump data including CGM data are collected through periodic data uploads. Users can upload either automatically (every night), manually, or at device download stations at clinics during the visits, based on the user's preference. As the pumps have a 3-month storage capacity, upload gaps smaller than 3-month will not lead to missing data. Apart from device data, CareLink Personal also contains data on self-reported gender (i.e. female, male) and self-reported age groups (i.e. ≤ 15 , 16-28, 29-42, 43-55, ≥ 56 years).

To be eligible for this study, PwT1D were required to have a registered CareLink Personal account in the Gulf Region. Furthermore, they needed to have ≥ 10 days of sensor glucose (SG) during the month of Ramadan 2022 (2 April to 1 May), as well as in the month before and after Ramadan. The 10-day cut-off is based on the recommended minimum to compute CGM metrics.¹²

2.3 | Main cohort

For the main analysis, CGM-based endpoints were aggregated for the months before, during and after Ramadan, and statistically compared. In addition, the study also reported endpoints based on two distinct time windows: one specific to the daytime during Ramadan and another specific to the night-time. The daytime window, which spans from 05.31 to 18.00 h, was established based on the Fajr (dawn) and Maghrib (sunset) prayer times for the first and last day of Ramadan in the most Northern, Western, Southern and Eastern cities within the Gulf region. We took the most conservative window to ensure that the fasting hours for all participants, regardless of their location, fell within the daytime window. As a result, the night-time window, which runs from 18.01 to 5.30 h, may include short periods of fasting for some users at the beginning or the end.

2.4 | Subcohorts

The main cohort was further broken down into multiple subcohorts. First, we defined a subcohort of users ≤ 15 and a subcohort of users > 15 years of age. This cut-off was chosen because Ramadan observation is only expected as of puberty, and ≤ 15 is the nearest CareLink Personal cut-off. Secondly, a subanalysis was performed by quartiles of manual daytime boluses to narrow down the study population to users that most certainly observed Ramadan. The quartile with the lowest mean of manual daytime boluses was expected to contain the highest proportion of Ramadan observers. The third subanalysis was performed to study the effect of GT settings on safety and efficacy. To avert hypoglycaemia, PwT1D are often advised to increase the GT during Ramadan and/or use the temporary target feature. For

this analysis, results were broken down into a subcohort that used a GT of 100 mg/dl for more than 95% of the time, and a subcohort that used a GT > 100 mg/dl for more than 95% of the time.

2.5 | Algorithm adaptation analyses

The algorithm adaptation analyses refer to analysing the agility of the algorithm in adapting to substantial changes in lifestyle. To do this, we aggregated data for each of the 7 days before and after the start of Ramadan separately and compared these visually. Similarly, this was also done for the last 7 days of Ramadan and the first 7 days after Ramadan (which includes the Eid al-Fitr, a 3-day celebration that marks the end of Ramadan).

2.6 | Statistics

Means and SDs were used to describe continuous variables, number of users and proportions to describe categorical variables. Statistical testing was only done in the main analysis for predefined metrics; we statistically compared metrics for glycaemic control as well as the total daily insulin dose (TDD) for the month of Ramadan with the month before, and for the month of Ramadan with the month after. In addition, we also compared metrics for glycaemic control during Ramadan daytime with Ramadan night-time. A paired t-test and 95% confidence intervals were used in cases where the normality assumption was met, and a Wilcoxon signed-rank test with first and third quartiles otherwise. The McNemar's test and 95% confidence intervals were used to compare the change in the proportion of subjects meeting glycaemic targets. A value of $p < .05$ was considered statistically significant. No corrections for multiple testing were performed in the predefined comparisons.

3 | RESULTS

In total, 449 PwT1D were eligible and included in the study, of which 247 self-reported to be ≤ 15 years and 202 to be > 15 years old.

3.1 | Main cohort

The effect of Ramadan on the glycaemia and insulin profile is shown in Figures 1 and 2, respectively. The glucose profile shows a profoundly different pattern during Ramadan when compared with the adjacent months. The month of Ramadan has two clear spikes at about 05.00 and 20.00 h, corresponding to the Suhur meal (before the Fajr prayer) and the Iftar meal (after the Maghrib prayer). The other 2 months both show a relatively flat pattern, which are identical to each other. A similar pattern is seen in the insulin profiles, with insulin peaks presenting earlier than the glycaemic peak, as expected.

The results for the Ramadan main analysis are shown in Table 1. In terms of glycaemic control, during Ramadan users reached a mean

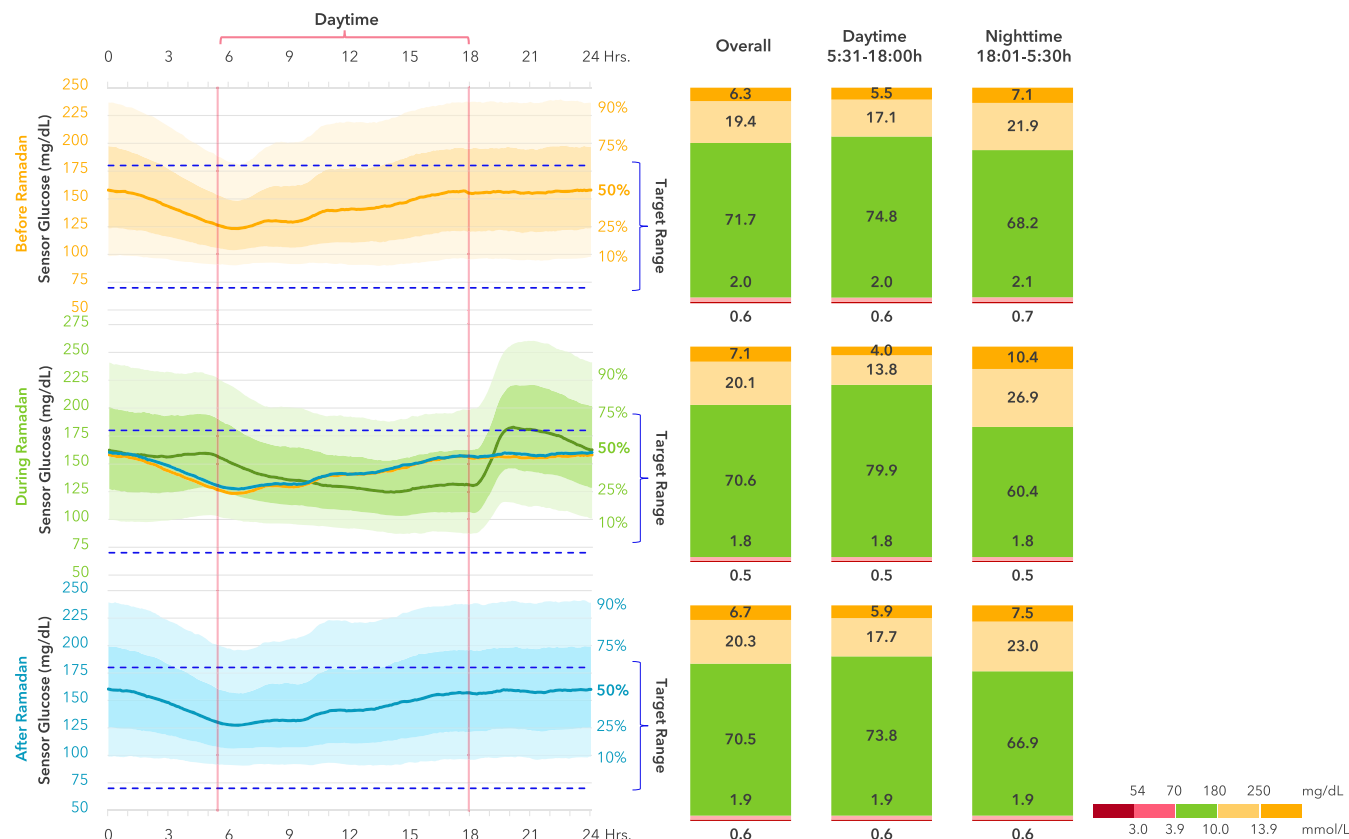


FIGURE 1 Glucose profiles and times in ranges in the month before, during and after Ramadan. The left middle plot not only shows the profile during Ramadan (green line), but also before (yellow line) and after (blue line).

SG of 152.6 ± 18.7 mg/dl, a mean SD of SG of 54.8 ± 12.2 mg/dl, a mean glucose management indicator (GMI) of $7.0 \pm 0.4\%$, a mean time between 70 and 180 mg/dl [time in range (TIR)] of $70.7 \pm 11.0\%$ and a mean time below 70 mg/dl (TB70) of $2.3 \pm 2.3\%$. Albeit the absolute differences were small, all the above metrics were statistically different from the metrics in the month before Ramadan ($p < .0001$ for all). When comparing the results during Ramadan to the month after Ramadan, only TB70 and time below 54 mg/dl (TB54) reached statistical significance ($p = .0103$ and $p = .0046$, respectively). The percentage of users reaching targets of TIR >70 , TB70 $<4\%$ and GMI $<7\%$ during Ramadan was 53.0%, 84.0% and 54.6%, respectively.

The more clinically significant differences were noted when comparing the fasting (daytime) and non-fasting (night-time) windows during Ramadan. The daytime TIR on average reached $80.0 \pm 10.7\%$, which was higher than the daytime TIR in the month before Ramadan ($74.7 \pm 11.5\%$, $p < .0001$) and the daytime TIR in the month after Ramadan ($73.9 \pm 11.1\%$, $p < .0001$). Interestingly, with only $2.3 \pm 2.4\%$ the TB70 remained low during Ramadan daytime. The night-time TIR reached to $60.4 \pm 15.3\%$, which was lower when compared with the night-time TIR in the month before ($68.3 \pm 12.4\%$, $p < .0001$) and after Ramadan ($67.0 \pm 12.6\%$, $p < .0001$) as well as when compared with the Ramadan daytime TIR ($p < .0001$). Time above range (TAR) 180 mg/dl was higher during Ramadan night-time (37.3

$\pm 16.3\%$) when compared with the month before Ramadan ($29.0 \pm 13.2\%$, respectively, $p < .0001$) and the month after Ramadan ($30.6 \pm 13.5\%$, $p < .0001$).

In terms of system characteristic, the percentage of time spent in automation remained high during Ramadan with $92.6 \pm 14.1\%$ and the number of automation exits remained low with 1.2 ± 1.4 exits per week, on average. During Ramadan, we observed a trend towards a more conservative GT setting, which was reflected by a decrease in the percentage of time spent with a GT of 100 mg/dl (from 48.1% to 41.6%) and a decrease in the percentage of users that spent $>95\%$ of the time with a GT of 100 mg/dl (from 35.2% to 25.4%). After Ramadan, these settings were mostly reset. For the active insulin time (AIT) no changes were observed.

In terms of insulin metrics, the TDD was not statistically different in the month before Ramadan when compared with the month of Ramadan, whereas the TDD was statistically higher in the month after Ramadan when compared with the month of Ramadan ($47.6 \pm 26.4\%$ vs. $45.2 \pm 25.1\%$, $p < .0001$). It must, however, be noted that the absolute difference was small. The mean total number of manual boluses per day ranged from 5.0 ± 2.3 to 5.3 ± 2.5 in the 3 months, and, as expected, we observed a decrease in the number of manual daily boluses during the daytime window (from 3.0 ± 1.5 manual boluses in the month before Ramadan to 1.5 ± 1.5 during

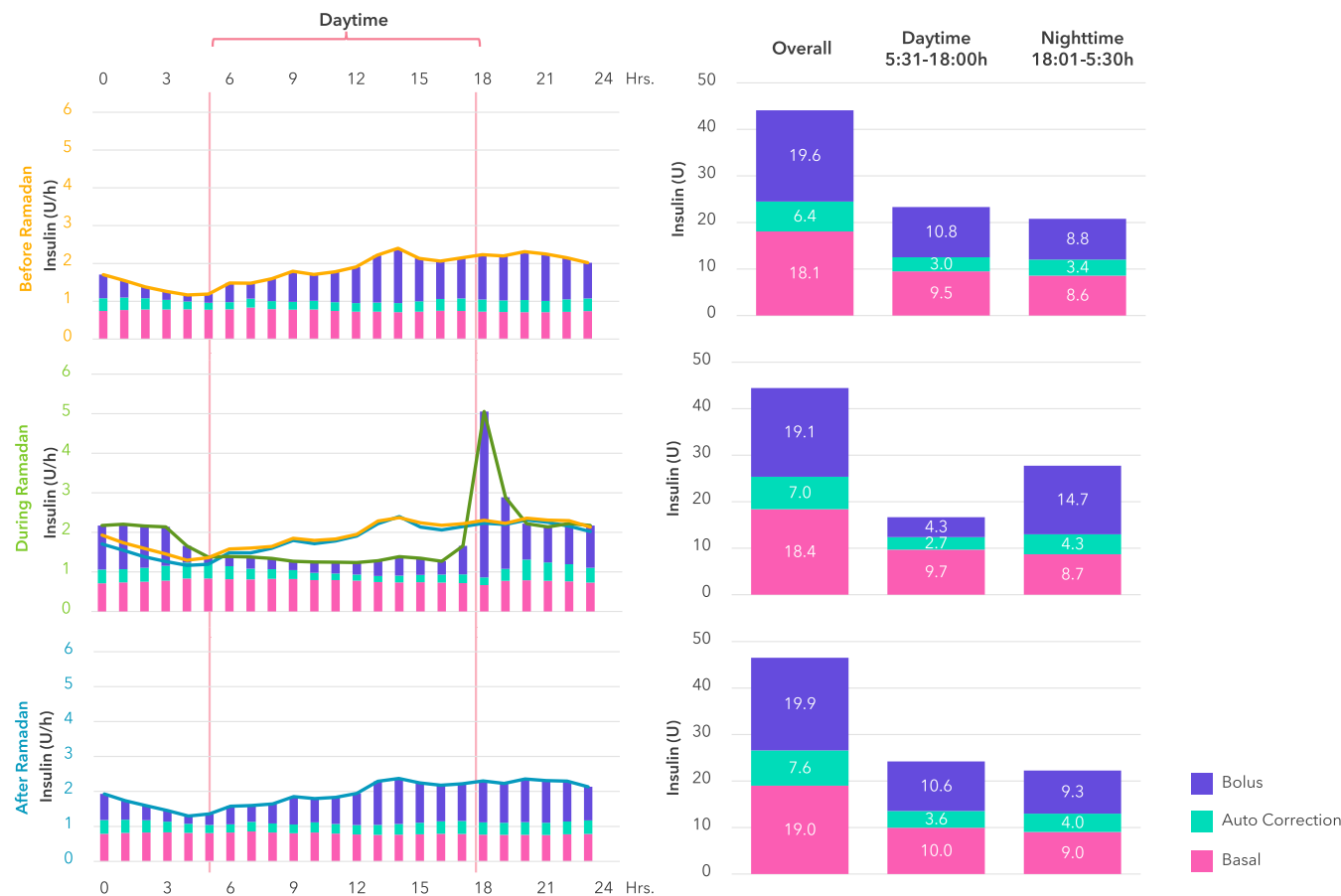


FIGURE 2 Insulin distribution in the month before, during and after Ramadan. The left middle plot not only shows the profile during Ramadan (green line), but also before (yellow line) and after (blue line).

Ramadan). The percentage of insulin delivered by automation was comparable between Ramadan and the adjacent months (ranging from $55.7 \pm 11.9\%$ to $56.3 \pm 12.1\%$).

3.2 | Subcohorts

The results for the subcohorts are shown in Table 2. First, the >15 years subcohort showed a TIR of $73.9 \pm 10.3\%$ (daytime TIR: $83.0 \pm 9.9\%$, night-time TIR: $64.2 \pm 15\%$) and a TB70 of $2.2 \pm 2.4\%$ (daytime TB70: $2.2 \pm 2.4\%$, night-time TB70: $2.3 \pm 2.9\%$). The TIR was better than that observed in the ≤ 15 years subcohort (TIR $68.0 \pm 10.9\%$, daytime TIR $77.6 \pm 10.7\%$, night-time TIR $57.4 \pm 14.8\%$). Secondly, the subcohort with the least manual daytime boluses (Q1), probably reflecting the highest percentage of users that actually observed to Ramadan, reached a TIR of $71.2 \pm 10.9\%$ (daytime TIR: $84.5 \pm 9.2\%$, night-time TIR: $56.8 \pm 16.3\%$), without compromising safety (TB70: $1.5 \pm 1.4\%$, daytime TB70: $1.4 \pm 1.5\%$, night-time TB70: $1.5 \pm 1.9\%$). Thirdly, safety was also kept in the subcohort with the lowest GT setting (100 mg/dl), as indicated by a TB70 of $2.3 \pm 2.2\%$ during the full day and a TB70 of $2.4 \pm 2.2\%$ during the daytime. For a country-specific breakdown, as well as a breakdown per different GT and AIT settings, we refer to the Supporting information.

3.3 | Algorithm adaptation analyses

The results for the algorithm adaptation analyses are shown in Figure 3. Data from the last 7 days before Ramadan and the first 7 days after Ramadan show that the average daily TIR fluctuates (between 72.8% and 67.3%) but does not have an apparent drop on the first day of Ramadan. In addition, TB70 remained $<3.0\%$ during all days. The adaptation profile at the end of Ramadan (which includes the last 7 days of Ramadan and the first 7 days after Ramadan) also shows a stable pattern per day in terms of the TIR; TIR ranged from 72.0% to 67.9%, and TB70 remained $<2.8\%$ during all days.

4 | DISCUSSION

This study presents an evaluation of the effectiveness and safety of the MiniMed 780G AID system among real-world users from the Gulf region during the 2022 Ramadan period. The glycaemia and insulin delivery patterns observed among MiniMed 780G system users during Ramadan differed substantially from those in the adjacent months. Specifically, two distinct spikes in hyperglycaemia and insulin delivery were evident during Ramadan, corresponding to the Suhur and Iftar meals. These altered patterns highlight the robustness of the real-

TABLE 2 Continuous glucose monitoring based metrics in subcohorts during Ramadan.

	Age, years		Daytime manual boluses				Glucose target, mg/dl	
	≤15	>15	Q1	Q2	Q3	Q4	100	>100
General								
N	247	202	112	111	113	113	114	127
Age groups, years; n (%)								
≤15	247 (100.0)		47 (42.0)	49 (44.1)	73 (64.6)	78 (69.0)	53 (46.5)	89 (70.1)
>15		202 (100.0)	65 (58.0)	62 (55.9)	40 (35.4)	35 (31.0)	61 (53.5)	38 (29.9)
Gender, n (%)								
Female	135 (54.7)	110 (54.5)	53 (47.3)	65 (58.6)	61 (54.0)	66 (58.4)	70 (61.4)	62 (48.8)
Male	112 (45.3)	92 (45.5)	59 (52.7)	46 (41.4)	52 (46.0)	47 (41.6)	44 (38.6)	65 (51.2)
System time, days	28.4 ± 2.9	28.0 ± 3.7	27.8 ± 4.4	28.6 ± 1.6	27.8 ± 4.3	28.7 ± 1.6	28.1 ± 3.6	28.5 ± 2.5
Glycaemic control								
Sensor glucose, mg/dl	156.3 ± 19.1	148.2 ± 17.1	153.6 ± 17.2	154.2 ± 17.6	156.2 ± 20.8	146.6 ± 17.9	146.4 ± 17.4	153.1 ± 16.8
SD of SG, mg/dl	57.8 ± 12.0	51.2 ± 11.5	53.9 ± 11.9	56.0 ± 11.6	57.7 ± 13.1	51.6 ± 11.5	52.3 ± 11.6	55.4 ± 12.0
Glucose management indicator, %	7.0 ± 0.5	6.9 ± 0.4	7.0 ± 0.4	7.0 ± 0.4	7.0 ± 0.5	6.8 ± 0.4	6.8 ± 0.4	7.0 ± 0.4
Time in range, % of time								
Time below 54 mg/dl	0.5 ± 0.7	0.5 ± 0.8	0.3 ± 0.4	0.5 ± 0.7	0.7 ± 1.0	0.5 ± 0.6	0.5 ± 0.8	0.5 ± 0.7
Time below 70 mg/dl	2.3 ± 2.2	2.2 ± 2.4	1.5 ± 1.4	2.2 ± 2.0	2.6 ± 2.7	2.8 ± 2.6	2.3 ± 2.2	2.4 ± 2.4
Time between 70 and 180 mg/dl	68.0 ± 10.9	73.9 ± 10.3	71.2 ± 10.9	69.8 ± 10.7	68.1 ± 11.6	73.6 ± 10.2	74.0 ± 10.3	70.5 ± 10.5
Time above 180 mg/dl	29.7 ± 11.6	23.8 ± 10.9	27.4 ± 11.2	28.0 ± 11.3	29.3 ± 12.2	23.6 ± 11.1	23.7 ± 11.0	27.2 ± 11.0
Time above 250 mg/dl	8.4 ± 6.7	5.5 ± 5.0	6.9 ± 6.1	7.5 ± 5.7	8.4 ± 7.5	5.4 ± 4.8	5.4 ± 5.8	7.2 ± 5.7
Users reaching targets, % of users								
TIR >70%	43.3	64.9	53.6	49.5	49.6	65.5	69.3	52.8
TB70 <4%	83.4	84.7	53.6	50.5	44.2	63.7	85.1	49.6
GMI <7%	47.0	63.9	94.6	87.4	79.6	74.3	71.9	81.1
Glycaemic control during daytime (05.31-18.00 h)								
Time below 54 mg/dl, %	0.5 ± 0.7	0.5 ± 0.9	0.3 ± 0.5	0.5 ± 0.8	0.6 ± 1.1	0.6 ± 0.7	0.5 ± 1.0	0.5 ± 0.7
Time below 70 mg/dl, %	2.4 ± 2.5	2.2 ± 2.4	1.4 ± 1.5	2.2 ± 2.1	2.6 ± 2.9	2.9 ± 2.7	2.4 ± 2.2	2.3 ± 2.5
Time between 70 and 180 mg/dl, %	77.6 ± 10.7	83.0 ± 9.9	84.5 ± 9.2	80.8 ± 9.8	77.0 ± 11.1	77.9 ± 10.9	83.4 ± 10.1	79.0 ± 10.6
Time above 180 mg/dl, %	20.0 ± 10.7	14.9 ± 9.9	14.1 ± 9.2	17.0 ± 9.9	20.5 ± 11.1	19.3 ± 11.5	14.2 ± 10.1	18.7 ± 10.4
Time above 250 mg/dl, %	5.0 ± 5.6	2.8 ± 3.8	2.8 ± 4.1	3.6 ± 3.7	5.5 ± 6.3	4.2 ± 5.0	3.1 ± 5.4	4.4 ± 4.6
Manual boluses, n/d	1.7 ± 1.6	1.1 ± 1.3	0.2 ± 0.1	0.6 ± 0.2	1.5 ± 0.3	3.5 ± 1.4	1.2 ± 1.3	1.9 ± 1.7

TABLE 2 (Continued)

	Age, years		Daytime manual boluses				Glucose target, mg/dl	
	≤15	>15	Q1	Q2	Q3	Q4	100	>100
Glycaemic control during night-time (18.01-05.30 h)								
Time below 54 mg/dl, %	0.5 ± 0.8	0.6 ± 0.9	0.3 ± 0.6	0.5 ± 0.9	0.7 ± 1.1	0.5 ± 0.7	0.6 ± 0.9	0.6 ± 0.8
Time below 70 mg/dl, %	2.2 ± 2.4	2.3 ± 2.9	1.5 ± 1.9	2.2 ± 2.7	2.6 ± 2.8	2.7 ± 2.9	2.3 ± 2.6	2.5 ± 2.7
Time between 70 and 180 mg/dl, %	57.4 ± 14.8	64.2 ± 15.0	56.8 ± 16.3	57.7 ± 14.5	58.4 ± 14.5	68.8 ± 12.5	63.8 ± 15.5	61.0 ± 14.1
Time above 180 mg/dl, %	40.3 ± 15.9	33.5 ± 16.1	41.7 ± 17.0	40.0 ± 15.6	39.0 ± 15.6	28.4 ± 13.6	33.9 ± 16.5	36.4 ± 15.0
Time above 250 mg/dl, %	12.0 ± 9.4	8.4 ± 8.0	11.4 ± 9.9	11.9 ± 8.9	11.7 ± 9.9	6.6 ± 5.8	8.0 ± 8.0	10.2 ± 8.2
Manual boluses, n/d	3.5 ± 1.5	3.5 ± 1.7	3.3 ± 1.3	3.6 ± 1.5	3.2 ± 1.5	3.8 ± 2.0	3.2 ± 1.5	3.4 ± 1.6
System characteristic								
Time in automation, %	94.1 ± 12.2	90.7 ± 15.9	94.5 ± 8.7	92.7 ± 10.7	90.3 ± 15.2	92.8 ± 19.1	95.0 ± 8.1	96.5 ± 6.3
Automation exits, n/w	1.1 ± 1.2	1.3 ± 1.6	1.2 ± 1.4	1.3 ± 1.1	1.4 ± 1.9	0.8 ± 0.9	1.0 ± 0.9	0.8 ± 0.9
SMBGs per day, n/d	2.9 ± 1.3	3.0 ± 1.2	2.8 ± 1.2	2.7 ± 1.1	3.0 ± 1.2	3.3 ± 1.6	2.7 ± 1.2	3.0 ± 1.4
Alarms per day, n/d	11.5 ± 6.2	10.1 ± 5.2	8.8 ± 4.4	10.4 ± 5.0	12.2 ± 5.7	12.0 ± 7.1	10.1 ± 5.1	11.1 ± 6.0
Glucose target, % of time								
100 mg/dl	34.8 ± 44.1	49.8 ± 45.5	40.2 ± 45.8	50.1 ± 44.7	37.4 ± 44.4	38.7 ± 45.8	97.5 ± 1.2	0.0 ± 0.1
110 mg/dl	27.6 ± 41.0	17.5 ± 34.9	24.7 ± 39.5	16.2 ± 33.3	29.3 ± 42.8	21.9 ± 37.9	0.0 ± 0.0	45.8 ± 47.9
120 mg/dl	29.4 ± 42.1	22.5 ± 37.9	25.7 ± 40.2	22.8 ± 38.7	25.3 ± 40.3	31.4 ± 42.2	0.0 ± 0.0	51.9 ± 47.7
150 mg/dl	4.0 ± 10.3	4.4 ± 10.0	5.1 ± 10.4	6.1 ± 12.8	2.6 ± 7.9	2.9 ± 8.6	0.2 ± 0.6	0.2 ± 0.5
Users with >95% in GT, % of users								
100 mg/dl	21.5	30.2	28.6	27.0	23.9	22.1	100.0	0.0
110 mg/dl	15.8	8.4	12.5	7.2	17.7	12.4	0.0	44.1
120 mg/dl	17.4	9.9	13.4	9.9	12.4	20.4	0.0	49.6
Active insulin time, % of time								
2 h	20.1 ± 39.5	30.6 ± 45.8	22.3 ± 40.9	31.5 ± 46.5	23.3 ± 41.8	22.1 ± 41.4	36.6 ± 47.9	13.1 ± 33.6
2-3 h	68.8 ± 45.2	56.6 ± 49.3	66.2 ± 46.6	54.1 ± 50.0	69.3 ± 45.2	63.5 ± 47.2	54.6 ± 49.5	68.5 ± 46.4
3-4 h	10.8 ± 29.8	12.5 ± 32.9	11.5 ± 30.9	14.4 ± 35.2	7.4 ± 25.3	13.0 ± 32.7	8.8 ± 28.4	17.6 ± 37.9
>4 h	0.4 ± 6.4	0.3 ± 4.5	0.0 ± 0.3	0.0 ± 0.0	0.0 ± 0.3	1.5 ± 11.1	0.0 ± 0.0	0.8 ± 8.9
Users with >95% in AIT, % of users								
2 h	18.6	29.7	20.5	30.6	22.1	21.2	36.0	12.6
2-3 h	65.6	55.4	64.3	54.1	66.4	59.3	52.6	67.7
3-4 h	8.9	12.4	9.8	14.4	6.2	11.5	8.8	17.3
>4 h	0.4	0.0	0.0	0.0	0.0	0.9	0.0	0.8

(Continues)

TABLE 2 (Continued)

	Age, years	Daytime manual boluses					Glucose target, mg/dl	
		Q1	Q2	Q3	Q4		100	>100
Insulin								
Carbohydrates, g/d	160.9 ± 63.5	177.5 ± 82.9	173.9 ± 67.9	154.9 ± 73.1	181.8 ± 76.5		176.6 ± 81.7	169.3 ± 67.8
Insulin to carbs, ratio	12.6 ± 7.4	8.8 ± 3.6	9.4 ± 4.2	11.4 ± 8.1	13.1 ± 6.9		9.8 ± 7.4	12.6 ± 6.3
Total daily insulin dose, U/day	40.2 ± 23.9	51.3 ± 25.3	51.4 ± 25.4	42.1 ± 18.9	39.7 ± 30.6		53.0 ± 25.3	37.3 ± 19.4
Insulin delivery, % of TDD								
Automatically	57.5 ± 12.1	54.8 ± 11.9	57.1 ± 12.1	58.0 ± 11.7	51.5 ± 12.0		57.8 ± 12.5	55.7 ± 11.7
Autobasal	40.5 ± 7.3	41.3 ± 8.1	41.5 ± 7.5	41.3 ± 7.1	38.2 ± 7.9		42.2 ± 7.5	39.2 ± 6.3
Autocorrection bolus	17.0 ± 7.1	13.5 ± 6.6	15.7 ± 6.9	16.7 ± 7.7	13.3 ± 6.8		15.6 ± 7.2	16.5 ± 7.5
Manual bolus	42.5 ± 12.1	45.2 ± 11.9	42.9 ± 12.1	42.0 ± 11.7	48.5 ± 12.0		42.2 ± 12.5	44.3 ± 11.7
Manual boluses, n/d	5.2 ± 2.2	4.7 ± 2.4	4.3 ± 1.5	4.7 ± 1.6	7.4 ± 2.6		4.5 ± 2.1	5.3 ± 2.2

Note: Values are presented as means ± SD.

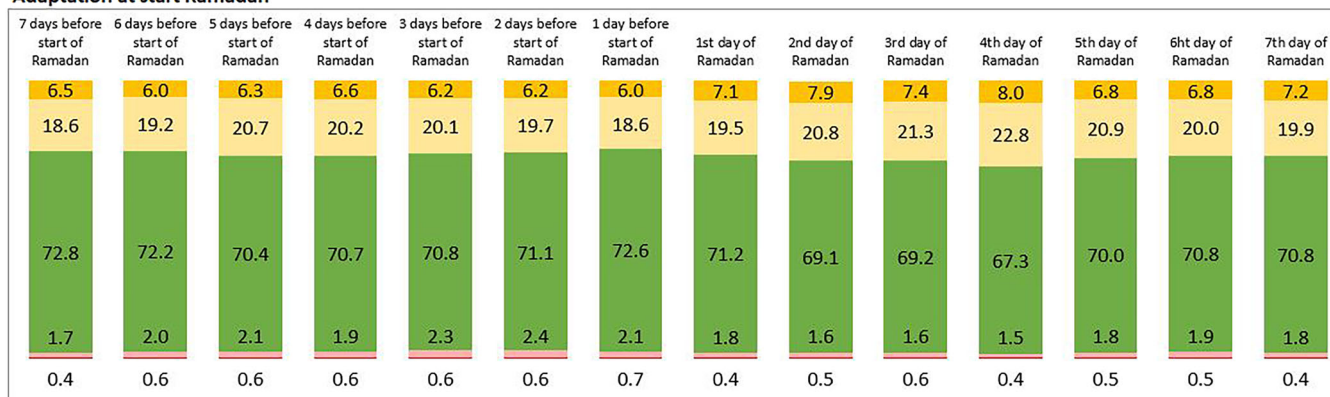
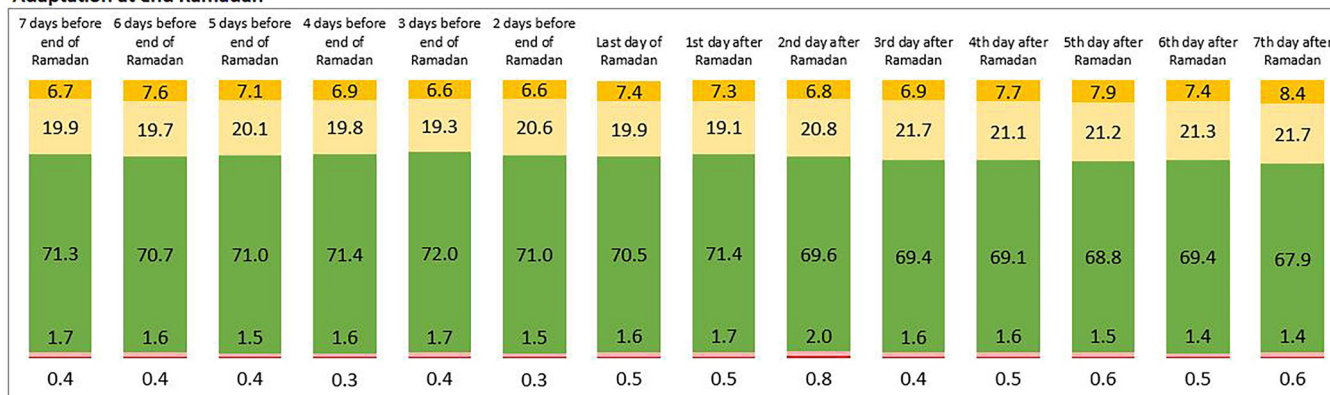
Abbreviations: AIT, active insulin time; GMI, glucose management indicator; GT, glucose target; n/d, number per day; n/w, number per week; Q, quartile; SG, sensor glucose; SMBG, self-monitoring blood glucose; TB70, time below 70 mg/dl; TDD, total daily dose; TIR, time in range.

world data collected through Carelink Personal and underscore the considerable challenge faced by PwT1D in achieving glycaemic control during Ramadan.

The key finding from this study is that the MiniMed 780G system effectively and safely controlled glucose levels during Ramadan, with no clinical differences compared with the months before and after Ramadan. During Ramadan, the MiniMed 780G users reached a mean SG of 152.6 mg/dl, GMI of 7.0%, TIR of 70.7% and TB70 of 2.3%. Although most metrics for glycaemic control exhibited statistical differences when compared with the adjacent months, the absolute differences were minimal and considered not clinically relevant. Notably, the CGM-based metrics fell well within international target criteria before, during and after Ramadan.¹² Furthermore, the study also demonstrated that younger individuals in the subgroup aged ≤15 years, who may not adhere to fasting, still exhibited safe and satisfactory glycemic control.

Despite the presumed risks of fasting for PwT1D, there was no increased risk of hypoglycaemia during the Ramadan daytime among the MiniMed 780G system users. The daytime TB70 and TB54 reached 2.3% and 0.5% respectively and were even significantly lower than that in the adjacent months (before: 2.6% and 0.6%, after: 2.4% and 0.6%; $p < .05$ for all). During Ramadan night-time, we observed a somewhat lower but still reasonable TIR (60.4%) when compared with the adjacent months (before: 68.3%, after: 67.0%; $p < .05$ for all). In parallel with this, there was a slight increase in TAR (37.3%, before: 29.0%, after: 30.6%; $p < .05$ for all), which is a well-known phenomenon.^{9,14} Based on the literature and the glycaemia pattern depicted in Figure 1, the elevated TAR during night-time is probably attributed to post-Iftar hyperglycaemia. This post-Iftar hyperglycaemia may be the result of the type and quantity of food consumed with Iftar and afterward, as well as the decision of users and health care professionals to change pump settings to more conservative values as a preventive measure against hypoglycaemia. This is confirmed by the data, as we observed a trend towards the use of more conservative GT; both the percentage of time spent with GT = 100 mg/dl and the percentage of users that spent more than 95% of the time with a GT = 100 mg/dl decreased when compared with the month before Ramadan (respectively, before: 48.1%, during: 41.6%, and before: 35.2%, during 25.4%). Interestingly, the subanalysis on GT settings revealed similar TB70 and TB54 among users that spent >95% of the time with a GT = 100 mg/dl and users that spent >95% of the time with a GT >100 mg/dl. Therefore, the changes in GT were largely unnecessary.

Ramadan was observed to have a clear impact on the insulin distribution patterns of MiniMed 780G system users. Although, the TDD (before: 45.8, during: 45.2) and the total number of manual boluses (before: 5.3, during: 5.0) remained relatively stable, there is a noticeable shift towards fewer manual boluses during daytime (before: 3.0, during: 1.5) and more manual boluses during night-time (before: 2.3, during: 3.5). Figure 2 underlines this by depicting distinct spikes in manual bolusing during Ramadan corresponding to the Suhur and Iftar meal. In addition, the figure also shows that the amount of insulin delivered by autocorrection nearly doubled during Ramadan night-time versus daytime. From these observations, we conclude that the

Adaptation at start Ramadan**Adaptation at end Ramadan****FIGURE 3** Daily time in ranges at the start and at the end of Ramadan.

overall positive outcomes of glycaemic control during Ramadan can be attributed, at least in part, to the increasing role of AID in mitigating profound lifestyle changes.

The safety profile of the MiniMed 780G system remained consistent even among the subgroup of users with the lowest number of manual daytime boluses (0.2 manual boluses). This subcohort probably included a higher proportion of individuals observing Ramadan, yet it exhibited a reassuring TIR of 71.2% (daytime TIR: 84.5%, night-time TIR: 56.8%) and a TB70 of 1.5% (daytime TB70: 1.5%, night-time-TB70: 1.5%). It is worth noting that the safety target of TB70 <4% and TB54 <1% was achieved across all subcohorts.

The MiniMed 780G system algorithm shows immediate adaptation to lifestyle changes. The algorithm adaptation analyses show that the times in ranges are relatively stable from the 7 days preceding Ramadan to the 7 days after its commencement. Similarly, this stability is observed from the last 7 days of Ramadan to the first 7 days after, which encompasses the celebrations of Eid al-Fitr. Considering that Ramadan encompasses unmatched lifestyle modifications, such as alterations in dietary habits, exercise routines and sleep patterns, we believe that the proven adaptive capability of the MiniMed 780G system can be extrapolated to other scenarios involving lifestyle changes.

The findings from this real-world analysis align with previous clinical studies conducted on the MiniMed 780G system during Ramadan.

Elbarbary and Ismail have reported excellent glycaemic control and safety in a randomized controlled trial.¹⁰ Half of the 42 included MiniMed 780G users were asked to keep the same settings before Ramadan (i.e. GT of 100 mg/dl and AIT of 2 h) while the others changed to more conservative settings during Ramadan (i.e. GT of 120 mg/dl and AIT of 3 h). The group with the most aggressive settings reached an average of 82% TIR, an average TB70 of 3%, and reported no severe hypoglycaemic (or diabetic ketoacidosis) events. Wannes et al., published a case-report, and described an 11-year-old child with T1D who fasted for two successive Ramadan seasons under two different insulin administration technologies (i.e. the MiniMed 640G predictive low glucose management system in 2021 and MiniMed 780G system in 2022).¹¹ The MiniMed 780G system showed better glycaemic control and a better safety pattern.

The findings of this study have potential implications for the current 'IDF-DAR Diabetes and Ramadan Practical Guidelines'.⁹ The current risk calculator provided by IDF-DAR assigns similar risk scores to PwT1D using multiple daily injections and those using insulin pumps and does not differentiate by type of insulin pump. However, our data reveal that users of the MiniMed 780G system do not experience a clinically relevant change in TIR, TBR or TAR during Ramadan, which contrasts with the observed changes in multiple daily injection users during Ramadan.⁸ This, along with the algorithm's rapid adaptation, holds clinical implications when counselling PwT1D regarding

fasting during Ramadan. In addition, the MiniMed 780G system simplifies pre-Ramadan counselling as it requires fewer manual actions. Therefore, we recommend that the type of insulin pump (i.e. AID systems) should be taken into consideration when using diabetes and Ramadan risk calculators.

A limitation of this study is the constraints of the data collected in CareLink Personal. Many socio-demographic variables are missing because of privacy regulations, including data on religion and the level of fasting adherence. Subanalyses were performed to raise the odds of having a subcohort with as many Ramadan observers as possible and results hereof showed very similar patterns to the main cohort. In addition, age and diabetes type are self-reported and cannot be affirmed. The study also possesses several strengths. It benefits from a large real-world study population derived from a well-documented data source, which helps minimize selection bias and enhances the generalizability of the findings.

5 | CONCLUSION

Despite the presumed risks of fasting for PwT1D, real-world evidence from MiniMed 780G users in the Gulf region showed relatively similar TIR, TBR and TAR values before, during, and after Ramadan. All CGM metrics remained within the international targets during Ramadan with no apparent increased risk of hypoglycaemia during the Ramadan fasting hours, and the algorithm adapted to the lifestyle changes immediately. Altogether, our study shows that MiniMed 780G AID system is effective, safe and fast in adapting to the substantial changes that occur in the daily routine of PwT1D during the month of Ramadan.

AUTHOR CONTRIBUTIONS

MAS, AArr, JC, TvdH and OC designed the study. AArr and JC analysed the data. TH wrote the manuscript. All authors interpreted and discussed the data and reviewed the manuscript. OC is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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CONFLICT OF INTEREST STATEMENT

MAS, GP, AAS, AAlg, MAH, DAM, AAdj, AAla, SAR and NA have served as speakers on Medtronic events and have served in Medtronic advisory boards. AArr, JC, WC, TVDH and OC are employees of Medtronic.

PEER REVIEW

The peer review history for this article is available at <https://www.webofscience.com/api/gateway/wos/peer-review/10.1111/dom.15389>.

DATA AVAILABILITY STATEMENT

Data is available upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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