REAL-WORLD EVIDENCE FROM 61,481 MINIMED™ 780G SYSTEM USERS IN EUROPE, MIDDLE EAST, AND AFRICA

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1. INTRODUCTION

Real-world studies increasingly receive recognition as a valuable source to provide information on the effectiveness and safety of medical products. When encompassing large and unbiased populations, they can complement the data generated from clinical trials that mostly include rather homogeneous populations and controlled environments.

2. AIM

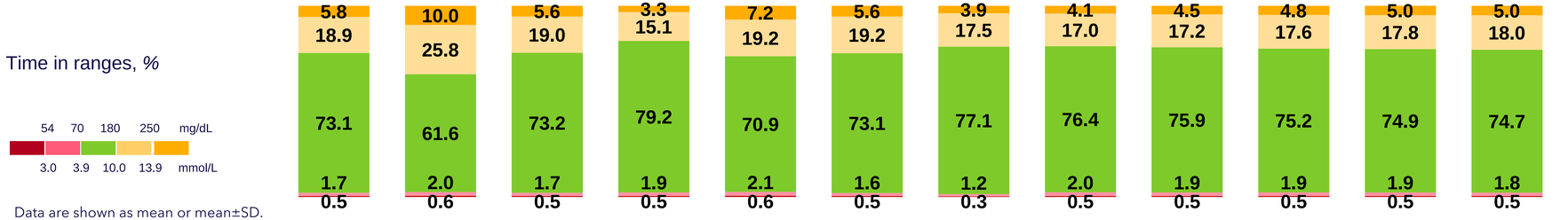
Here, we report on the real-world performance of the MiniMed™ 780G advanced hybrid closed-loop (AHCL) system in users from Europe, the Middle East, and Africa (EMEA).

3. METHODS

CareLink™ Personal data (Aug2020-Dec2022) from users with ≥10 days of sensor glucose (SG) data after AHCL initiation were assessed across cohorts. CGM endpoints were aggregated for an overall cohort. An improvement cohort included users who also had ≥10 days of SG data before AHCL initiation (i.e., pre-AHCL initiation). The recommended settings cohort used a glucose target (GT) = 100 mg/dL and active insulin time (AIT) = 2 hours for >95%. CGM data were also determined for a cohort based on self-reported age. For users with ≥10 days of SG in each month up to one year, aggregations were shown per month.

Figure. Continuous Glucose Monitoring-based Endpoints for All Cohorts

	Overall	Pre-AHCL initiation	Post-AHCL initiation	Recommended Settings*	Age ≤15	Age 16-55	Age ≥ 56	Month 1	Month 3	Month 6	Month 9	Month 12
Users, n	61,481	15,395	15,395	4,392	14,577	35,366	7,415	11,617	11,617	11,617	11,617	11,617
Time in AHCL, %	90 ± 16	--	90 ± 17	94 ± 11	91 ± 15	89 ± 17	94 ± 12	95 ± 12	95 ± 13	94 ± 13	94 ± 13	94 ± 13
Sensor glucose, mg/dL	151 ± 17	165 ± 25	150 ± 16	140 ± 12	152 ± 16	151 ± 17	147 ± 14	144 ± 15	145 ± 16	146 ± 16	147 ± 17	148 ± 17
Standard deviation of SG, mg/dL	52 ± 11	57 ± 12	52 ± 11	47 ± 9	57 ± 11	51 ± 10	47 ± 9	49 ± 10	49 ± 10	50 ± 11	50 ± 11	50 ± 11
Coefficient of variation, %	34 ± 5	35 ± 5	34 ± 5	33 ± 5	37 ± 5	34 ± 4	32 ± 4	34 ± 5	34 ± 5	34 ± 5	34 ± 5	34 ± 5
GMI, %	6.9 ± 0.4	7.3 ± 0.6	6.9 ± 0.4	6.7 ± 0.3	6.9 ± 0.4	6.9 ± 0.4	6.8 ± 0.3	6.8 ± 0.4	6.8 ± 0.4	6.8 ± 0.4	6.8 ± 0.4	6.8 ± 0.4
Users with TIR >70%, %	65.4	33.9	64.7	88.5	56.5	66.0	79.2	77.9	75.0	72.1	71.0	70.6
Users with TBR <4%, %	86.5	78.7	86.0	84.4	78.9	88.0	93.7	80.8	82.7	82.9	83.1	83.5
Users with GMI <7%, %	63.8	29.5	66.1	88.4	61.2	62.9	72.9	78.7	75.3	72.2	70.9	69.8



Data are shown as mean or mean±SD.
AHCL=Advanced hybrid closed loop; GMI=Glucose management indicator; SG=Sensor glucose; TIR=Time in range (70-180 mg/dL), TBR= Time below 70 mg/dL
*Recommended settings were glucose target of 100 mg/dL and active insulin time of 2 hours used for >95% of the time.

4. RESULTS

The glycemic outcomes of the overall and improvement cohorts, those using the recommended settings, and individuals stratified by self-reported age are shown (**Figure**). The overall group had an SG of 151±17 mg/dL, glucose management indicator (GMI) of 6.9±0.4%, time in range (TIR) of 73.1±10.1%, and time below 70 mg/dL (TBR) of 2.2±1.8%. In addition, 63.8%, 65.4% and 86.5% of users reached the targets of GMI<7%, TIR>70%, and TBR<4%, respectively. Compared to pre-AHCL initiation, TIR increased by 11.6% (P<0.0001), after AHCL initiation. For users with >95% of time using the recommended settings, TIR was 79.2% and TBR was 2.4%. Glycemic control met the ADA-recommended TIR target of >70% in all age groups (TIR for ≤15yr: 70.9%, for 16-55yr: 73.1% and for ≥56yr: 77.1%) and overall control was sustainable over time (TIR >74% for each month).

5. CONCLUSIONS

- In 61,481 real-world MM780G users from EMEA, mean glycemic control exceeded ADA recommended targets.
- Results were consistent across age-groups and were sustainable over time. Based on the TIR (79.2%) of those using recommended settings without increasing TBR, we encourage a GT of 100 mg/dL with an AIT of 2 hours in most users of the MM780G system.

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The MiniMed™780G system algorithm includes technology developed by DreaMed.

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