Professional
Continuous Glucose Monitoring
Implementation Playbook

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Overview and Introduction to Professional CGM

Before you begin your journey to incorporate Professional Continuous Glucose Monitoring (Professional CGM) into your practice, it is important to have a thorough understanding of this technology. The following pages describe Professional CGM and introduce this Playbook.

Introduction to the
Professional CGM Implementation Playbook

Continuous glucose monitoring, whether personal or professional, is another tool that can help to optimize diabetes management. Although not a new technology, CGM devices are constantly evolving and improving. With the right guidance, Professional CGM can be incorporated into any practice, large or small, specialized or general.

This Playbook brings together fragmented information available from multiple sources to provide an inclusive and unbiased approach to implementation of Professional CGM into your practice. It includes a step-by-step approach to implementation, additional resources and the latest research.

Who Is This Playbook Written For?

This Playbook is for primary care providers and diabetes educators who have an interest in using Professional CGM in their practices.

How Will This Playbook Benefit Me?

Implementation of an efficient and effective Professional CGM Program can be complicated and confusing. The Playbook is designed to help you successfully implement Professional CGM into your practice.

How Do I Utilize This Playbook?

The Playbook is organized into five sections that will assist you in your journey to implement Professional CGM.

Will The Information In This Playbook Become Outdated?

Because of rapid changes in technology and practice recommendations, this Playbook is intended to be a living document and will be reviewed and updated annually, at a minimum, to reflect new information and replace outdated information. Look for the Last Updated date on the second page of the manual to ensure you have the most updated version.

Introduction to
Continuous Glucose Monitoring (CGM)

Continuous glucose monitoring has become more widely adopted and utilized in recent years. Devices continue to improve in accuracy, reliability and convenience and insurance coverage is more widespread. Continuous glucose monitoring is considered a standard of care for people treated with intensive insulin programs.

Continuous glucose monitors measure interstitial fluid glucose levels and display numerical and graphic data regarding current glucose status, along with current and projected trends in the glucose. The projected future glucose trend is depicted by directional arrows. This allows users to proactively respond to blood glucose data rather than waiting for hyper or hypoglycemia to develop, therefore offering the ability to take preventive action to avoid hyper or hypoglycemia.

Personal CGM vs. Professional CGM

Continuous glucose monitoring devices are either owned by the user for personal use or owned by the health care center for professional use. Some continuous glucose devices link to other compatible devices, such as insulin pumps, blood glucose meters, smart phones, automated insulin-dosing systems and smart pens. Most CGM devices may be used as stand-alone devices. Some of the devices require periodic calibration with finger stick glucose checks.

Consumers who own personal CGM devices utilize the data in real time to make decisions about their diabetes management. The devices display trend arrows, indicating whether there is a pattern of rising or falling glucose to assist them in problem solving. Clinicians analyze retrospective data, sometimes combined with a user diary or log to gain insights into glycemic patterns.

> Three CGM devices are currently available for Professional CGM (July 2020)
> - Abbott Freestyle Libre Pro
> - Dexcom G6 Pro
> - Medtronic iPro 2

Blinded vs. Unblinded Mode

Professional CGM can be performed in the "blinded" or "unblinded" mode. Unblinded CGM allows people with diabetes to see their glucose data and make treatment decisions about it in real time. Blinded CGM use allows for the capture of glucose data without influencing the individual's behavior in the moment. Reviewing blinded CGM data with the person with diabetes can produce many "aha moments", which allows for them to understand how their medications, diet and activity impact their glycemic control.

Of the 3 available Professional CGM's, only Dexcom allows for both blinded and unblinded mode. The considerations for each are covered in Step 4 in Part 2 of this Playbook.

Abbott Freestyle Libre Pro

Dexcom G6 Pro

Medtronic iPro2

Components

The Abbott Freestyle Libre Pro consists of a disposable combined wired glucose sensor/transmitter and a separate touchscreen reader device. The reader for Libre Pro is only used to activate the sensor, but does not go home with the individual. When the sensor is returned, the clinic uses the reader to upload data from the sensor.

The Dexcom G6 Pro CGM consists of three components: a disposable wired sensor which is inserted in the subcutaneous tissue via an applicator, a disposable data transmitter which is attached to the sensor after insertion and a reader that verifies session start and allows subsequent data upload to CLARITY by the healthcare professional. For use in the unblinded mode, real-time glucose data can be viewed on a smartphone using the Dexcom G6 app.

The Medtronic iPro 2 consists of a disposable wired sensor and a data transmitter, which is attached to the sensor.

IMPORTANT NOTE:

The data transmitter on the Medtronic iPro 2 needs to undergo a cleaning process after being placed on a person with diabetes before the next use.

Comparison of Professional CGM Devices Currently Available

Features	Abbott Freestyle Libre Pro	Dexcom G6 Pro	Medtronic iPro2
Blinded or Unblinded	Blinded	Either	Blinded
Wear Time	14 days	10 days	6 days
Calibration Required?	0	0	3-4 times daily
Components	Disposable wired sensor/transmitter Separate touchscreen reader device that does not go home with the person with diabetes	Disposable wired sensor/transmitter Separate touchscreen reader device that does not go home with the person with diabetes	Disposable wired sensor Data transmitter attached to the sensor
Care Between Use	Disposable sensor/ transmitter	Disposable sensor/ transmitter	Transmitter must be cleaned and disinfected
Insertion	Single step process with auto-inserter	Two-step process which includes inserting sensor and attaching transmitter	Multi-step process which includes inserting and taping both the sensor and transmitter
Site	Upper Arm	Abdomen	Abdomen
Downloading/ Data Reports	LibreView	CLARITY	Carelink

Effectiveness of CGM

Multiple research studies confirm the effectiveness of continuous glucose monitoring. Randomized controlled trials have demonstrated decreased HbA1C and glycemic variability, increased time in range of target glycemia, decreased time in hypoglycemia range and reduction in hypoglycemic events.

Studies have been performed with multiple populations and different device types: people with type 1 and type 2 diabetes, adults and children, personal and Professional CGM. Dr. Anne Peters, Endocrinologist at the Keck School of Medicine at USC, provided a detailed review of CGM studies and outcomes in the _Role of Continuous Glucose Monitoring in Diabetes Treatment_ supplement published by the American Diabetes Association _(Chart used by permission, American Diabetes Association, 2018)._

Study	Design	Primary Outcome/ Type of CGM	A1C Outcome	Hypoglycemia Change/Other
ADULTS WITH T1D: A1C PRIMARY OUTCOME				
Beck et al. (1,2)	• Adults with T1D on MDI • n = 158 • Baseline A1C: ~8.6% • Parallel arms, 24 weeks	A1C reduction / Dexcom G4 Platinum	−0.6%, P<0.001	• Time <70 mg/dL was 43 vs. 80 min/day, P = 0.002 • No difference in severe lows
Lind et al. (3)	• Adults with T1D on MDI • n=161 • Baseline A1C: 8.6% • Crossover, 26-week arms	A1C reduction / Dexcom G4 Platinum	−0.43, P <0.001	• Numerically less time in a hypoglycemic range with CGM
Sequeira et al. (4)	• Underserved adults with T1D MDI • n = 25 • Baseline A1C: 8.5% • Crossover, 28-week arms	A1C reduction / Dexcom SEVEN	No significant difference be-tween groups	• No change in rates of hypoglycemia
Tumminia et al. (5)	• Adults with T1D on MDI or CSII • n = 20 • Baseline A1C: ~8.65% • Crossover, 24-week arms	A1C reduction / Medtronic Guardian REAL-Time	Only analyzed 14 patients who used CGM ≥40% of the time; in these patients, there was a significant reduction in A1C (P <0.05)	• Risk for hypoglyce-mia was reduced (time sent<70 mg/dL/day), P<0.05
ADULTS WITH T1D: HYPOGLYCEMIA PRIMARY OUTCOME				
Bolinder et al. (6)	• Adults with T1D on MDI or CSII • n = 241 • Baseline A1C: 6.7% • Parallel arms, 6 months	Change in time in hypoglycemic range (<70 mg/dL) / Abbott FreeStyle Libre	NS	• Overall, 38% reduc-tion in time in hypogly-cemia (−1.24 hours/day, P <0.0001) • Time in range (3.9–10.0 mmol/L [70–180 mg/dL]; mean difference) improved by 1.0 ± 0.30 hour, P = 0.0006

Hermanns et al. (7)	• Adults with T1D, most on MDI • n = 41 • Baseline A1C: 8.2% • Crossover design, 5-day arms; patients were free-living within inpatient research setting	Proportion of time spent hypoglycemic / Dexcom SEVEN PLUS	N/A	Reduction in time in hypoglycemic range: 125 ± 89 vs. 181 ± 125 min/day, P = 0.005
van Beers et al. (8)	• Adults with T1D on MDI or CSII with a Gold score ≥4 • n = 52 • Baseline A1C: 7.5% • Crossover, 16-week arms	Mean difference in time in range (4–10 mmol/L [72–180 mg/dL]) / Medtronic Enlite with a MiniMed Paradigm Veo system (used as a monitor)	NS	• Reductions in hypo-glycemia (≤3.9 mmol/L [70.2 mg/dL]) –4.7%, P <0.0001 • Severe hypoglycemia: 14 events with CGM vs. 34 events with SMBG, P = 0.033 • Time in range (mean difference) improved by 9.6%, P = 0.0001
ADULTS AND CHILDREN WITH T1D: A1C/TIME IN RANGE PRIMARY OUTCOME				
Battelino et al. (9)	• Adults and children with T1D on CSII • n = 153 • Baseline A1C: 8.1% for adults, 8.6% for children • Crossover, 6-month arms	A1C reduction / Medtronic Guardian REAL-Time	A1C difference –0.43% in favor of sensor on, P <0.001	• Time spent <3.9 mmol/L (70.2 mg/dL) was 19 vs. 31 min/day, P = 0.009 • Four severe hypogly-cemic episodes in sensor on mode, two in sensor off mode
Deiss et al. (10)	• Adults and children with T1D on MDI or CSII n = 156 • Baseline A1C: 9.5% in arm 1, 9.7% in arm 2 • Three parallel arms: continuous CGM (arm 1) vs. biweekly 3-day CGM (arm 2) vs. control for 3 months	A1C reduction / Medtronic Guardian REAL-Time	Arm 1: –0.6%, P = 0.003; Arm 2: no difference in A1C	One episode of severe hypoglycemia in each arm
JDRF CGM Study Group (11)	• Adults and children with T1D on MDI or CSII • n = 322 • Three age-groups: ≥25 years (n = 98), 15–24 years (n = 110), and 8–14 years (n = 98) • Baseline A1C: ≥25 years, 7.6%; 15–24 years, 7.9–8.0%; and 8–14 years, 7.9–8.0% • Parallel arms, 26 weeks	A1C reduction / DexCom SEVEN, Medtronic MiniMed Paradigm REAL-Time insulin pump and CGMS, and Abbott FreeStyle Navigator	A1C differ-ence: in those ≥25 years of age, –0.53%, P <0.001; in those <25 years of age, no difference A1C response related to use of CGM	No difference in time spent in a hypoglycemic range or in number of severe hypoglycemic episodes
O'Connell et al. (12)	• Adults and adolescents with T1D on CSII • n = 55 • Baseline A1C 7.3% for intervention group, 7.5% for control group • Parallel arms, 3 months	Time in range during the 3-month study period / Medtronic MiniMed Paradigm REAL-Time insulin pump and CGMS	• No differ-ence in primary outcome • A1C was –0.43% lower in the CGM group, P = 0.009 • Greater re-duction in group with more use	No difference in time in range, variability, or hypoglycemia

ADULTS AND CHILDREN WITH T1D: HYPOGLYCEMIA PRIMARY OUTCOME				
JDRF CGM Study Group (13)	• Adults and children with T1D on MDI or CSII • n = 129 • Baseline A1C: 6.4% for CGM group, 6.5% for control group • Parallel arms, 26 weeks	Change in time ≤70 mg/dL / DexCom SEVEN, MiniMed Paradigm REAL-Time insulin pump and CGMS, and Abbott FreeStyle Navigator	A1C treatment difference favoring CGM, P <0.001	• Time ≤70 mg/dL numerically less frequent (54 vs. 91 min/ day) but not significant, P = 0.16 • Median time with blood glucose ≤60 mg/ dL was 18 vs. 35 min/ day, P = 0.05 • Severe hypoglycemia 10 and 11% for CGM and control groups, respectively, P = 1.0
Battelino et al. (14)	• Adults and children with T1D on MDI or CSII • n = 120 • Baseline A1C: 6.9% • Parallel arms, 26 weeks	Time spent in hypoglycemic range / Abbott FreeStyle Navigator	A1C treatment difference favoring CGM: –0.27%, P = 0.008	• Time spent <63 mg/ dL shorter in CGM group; ratio of means 0.49, P = 0.03 • No severe hypoglycemia
Heinemann et al. (15)	• Adults and children with T1D on MDI with a history of impaired hypoglycemia awareness or severe hypoglycemia • n = 149 • Baseline A1C: 7.3% for control group, 7.6% for CGM group • Parallel arms, 26 weeks	Baseline-adjusted hypoglycemia events (glucose ≤3.0 mmol/L [54 mg/dL] for ≥20 minutes) / Dexcom G5 Mobile	No difference in A1C	Adjusted between-group difference in low glucose events: 0.28, P <0.0001
CHILDREN WITH T1D				
Ludvigsson et al. (16)	• Children with T1D on MDI or CSII • n = 27 • Baseline A1C: ~7.7% • Cross-over, 12-week arms; wore CGM for 3 days every 2 weeks	A1C reduction/ Medtronic CGMS	A1C difference at 12 weeks during open vs. blind CGM: ~–0.39%, P = 0.011	No significant differences in hypoglycemia
Chase et al. (17)	• Children with T1D • n = 200 • Baseline A1C: 8.0% • Parallel arms, 6 months	A1C reduction / GlucoWatch G2 Biographer	No significant change in A1C	Sensor use declined from 2.1 to 1.5 times/ week because of skin ir-ritation and other issues
ADULTS WITH T2D				
Beck et al. (18)	• Adults with T2D on MDI • n = 158 • Baseline A1C: 8.5% • Parallel arms, 24 weeks	A1C reduction / Dexcom G4 Platinum with an enhanced algorithm	Adjusted mean A1C difference: –0.3%, P = 0.022	No change in hypoglycemia
Ehrhardt et al. (19)	• Adults with T2D not on prandial insulin (half on oral medication alone) • n = 100 • Baseline A1C: 8.2% for SMBG group, 8.4% for CGM group • Parallel arms, 2 weeks on/1 week off, 4 cycles over 12 weeks	A1C reduction / Dexcom SEVEN	Difference in A1C: –0.6%, P = 0.002	• Hypoglycemia data NA • Most improvement in people who used CGM per protocol
Hermanns et al. (7)	• Adults with T2D on prandial-only insulin on MDI or CSII • n = 224 • Baseline A1C: 8.74% in intervention group, 8.88% in control group • Parallel arms, 2:1 randomization, 6 months	A1C reduction / Abbott FreeStyle Libre	No difference in A1C overall; difference in A1C if <65 years of age, P = 0.03	Time in hypoglycemia (<70 mg/dL) was reduced by 43%, P = 0.000

Yoo et al. (21)	• Adults with T2D on oral agents or insulin • n = 65 • Baseline A1C: 8.7% in SMBG group, 9.1% in CGM group • Parallel arms, real-time CGM for 3 days once per month for 12 weeks	A1C reduction / Medtronic Guardian REAL-Time	Improvement in A1C greater in CGM group, ~0.5%, P = 0.004 (CGM: from 9.1 ± 1.0 to 8.0 ± 1.2%, P <0.001; SMBG: from 8.7 ± 0.7 to 8.3 ± 1.1%, P = 0.01)	• No significant changes in hypoglycemia • In real-time CGM, reduced caloric intake, weight, BMI, and postprandial glucose level; increased physical activity
ADULTS WITH T1D OR T2D				
Garg et al. (22)	• Adults with T1D or T2D on insulin • n = 91 • Baseline A1C: 7.6% in control group, 8.0% in CGM group • Parallel arms, 3-day CGM for three consecutive 72-hour periods	Time spent in high, low, and target glucose zones / Dexcom STS sensor	• 23% less time in hyperglycemia (≥240 mg/dL) • 26% increase in time in range (81–140 mg/dL) • P <0.001 for each comparison	CGM group spent 21% less time in hypoglycemia (<55 mg/dL), P <0.0001
New et al. (23)	• Adults with T1D or T2D on MDI or CSII • n = 160 • Baseline A1C: 8.2% • Parallel arms, 100 days	Time spent outside of target range / Abbott FreeStyle Navigator; 1/3 CGM with no alarm, 1/3 CGM with alarm, 1/3 SMBG	No difference in A1C or time spent outside of target range	Less time in hypoglycemia range in group with alarms compared to SMBG group, P = 0.03
Cooke et al. (24)	• Adults with T1D or T2D treated with at least twice-daily insulin injections • n = 404 • Baseline A1C: 9.1% • Parallel arms, 18 months; GlucoWatch group wore device at least four times in the first 3 months and then as needed; Medtronic group wore device for 72 hours three times during first 3 months and on three more occasions thereafter	A1C reduction / GlucoWatch G2 Biographer vs. Medtronic MiniMed CGMS (blinded)	No significant difference in A1C reduction	No reduction in hypoglycemia; possibly an increase
PREGNANT PATIENTS WITH T1D, T2D, OR GDM				
Feig et al. (25)	• Adult women with T1D on MDI or CSII who were pregnant or planning pregnancy • n = 325 (215 pregnant, 110 planning pregnancy) • Baseline A1C: 6.83% in CGM group and 6.95% in control group (pregnant) and 7.57% in both CGM and control group (planning pregnancy) • Parallel arms, to 34 weeks in pregnant women; for 24 weeks in those planning pregnancy	A1C reduction / Medtronic Guardian REAL-Time or Min-iMed MiniLink	A1C difference –0.19%, P = 0.0207 in pregnant women; no A1C difference in women planning pregnancy	• Comparable severe hypoglycemia events (18 vs. 21) and time spent hypoglycemic (3 vs. 4%) • Neonatal health outcomes: fewer LGA babies, fewer neonatal ICU stays for >24 hours, and fewer neonatal hypoglycemia events
Secher et al. (26)	• Adult women with T1D or T2D who were pregnant • n = 154 • Baseline A1C: 6.6% in CGM group, 6.8% in control group • Parallel arms, 6 days of CGM at 8, 12, 21, 27, and 33 weeks vs. routine care	LGA babies / Medtronic Guardian REAL-time CGM with Sof-Sensor	No difference in A1C	• No difference in number of LGA babies • No difference in hypoglycemia

| Wei et al. (27) | • Adult women with GDM at 24–28 weeks of pregnancy
• n = 106
• Baseline A1C: 5.8% in SMBG group, 5.7% in CGM group
• Parallel arms; women were asked to wear CGM intermittently early (second trimester) or late (third trimester) or perform SMBG | Prenatal or obstetrical outcomes / Medtronic Gold CGMS | No significant reduction in A1C | • No difference in obstetrical outcomes
• Some reduction in maternal weight gain |

JDRF, Juvenile Diabetes Research Foundation; LGA, large-for-gestational-age; NA, no applicable; NS, non-significant; T1D, type 1 diabetes; T2D, type 2 diabetes.

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Guidelines/Position Statements Pertaining to CGM

AADE 2018 Practice Paper	ADA 2019	Endocrine Society 2016	AACE/ACE 2016	International Consensus 2017
Diabetes educators provide the coaching needed to help people with diabetes reap the benefits of CGM technology by utilizing the information to make smarter diabetes management decisions, reduce risk of hypoglycemia and hyperglycemia and thereby improve the quality of life.	Real-time CGM in conjunction with intensive insulin regimens is a useful tool to lower HbA1C in adults with type 1 diabetes who are not meeting glycemic targets. Real-time CGM may be a useful tool in those with hypoglycemia unawareness and/or frequent hypoglycemia.	Real-time CGM is recommended for adults with type 1 diabetes who are willing and able to use device on a nearly daily basis. Short-term, intermittent, real-time CGM is recommended for adult patients with type 2 diabetes (not on prandial insulin) who have HbA1C greater than or equal to 7.0%.	CGM is recommended for adult and pediatric patients with type 1 diabetes, particularly for those with history of severe hypoglycemia and hypoglycemia unawareness, and to assist in the correction of hyperglycemia in patients not at goal. There are no recommendations for patients with type 2 diabetes due to limited data.	CGM should be considered in conjunction with HbA1C monitoring for glycemic status assessment and therapy adjustment for all patients with type 1 diabetes and patients with type 2 diabetes treated with intensive insulin therapy who are not achieving glucose targets, especially if the patient is experiencing problematic hypoglycemia.

Benefits of Professional CGM
Intermittent use of Professional CGM has many benefits to the person with diabetes and the health care provider including:
- Identification of extremes in blood glucose levels
- Identification of Time in Range "TIR" of blood glucose results and if individual person with diabetes is meeting their desired targets
- Assessment of nocturnal glucose patterns
- Assessment of how well the current diabetes treatment plan is working and assess for need to change treatment plan
- Use as a teaching tool to help the person with diabetes understand the effects of factors such as food intake, exercise and diabetes medications on glucose levels
- May use as a test run to see if the individual would want to own a personal CGM; some insurances may require this

Candidate Selection
Many people with diabetes can benefit from an evaluation with Professional CGM.
Some good examples include those with:

- Gastroparesis
- Discordant HbA1C and fingerstick glucose readings
- Post-prandial hyperglycemia
- Hypoglycemia unawareness
- Pregnancy (Note: This is not approved.)
- Lack of regular monitoring of fingerstick glucose levels
- Renal disease

Additionally:
- Finger stick data is limited; CGM allows the HCP and person with diabetes to see BG 24/7
- Those who need to do multiple finger sticks daily
- When the HCP needs more data
- When individuals are considering personal CGM
- When insurance will not cover personal CGM, only Professional CGM

Case Study 1

Robert G. is a 66-year-old male with a 5-year history of Type 2 diabetes followed by primary care. Weight 201 pounds and BMI 32.44. Diabetes medications: Basaglar 26 units every night and Humalog 8 units before meals. A1C was 6.9% but his home glucose readings were higher than 200 mg/dl whenever he checked them, which sometimes was only once daily in the evening after work. His PCP ordered a diagnostic CGM because blood glucose values and A1C did not match.

He wore the Libre Pro CGM for 12 days and kept a detailed food, medication and activity log.

The 12-day report showed that his blood glucose levels were dropping low overnight and also in the afternoon when he skipped lunch. His blood glucose values trended high before dinner. He admitted to snacking in the late afternoon if he was feeling a bit light-headed after not having had time to eat lunch. The snacks he had written down tended to be 30-60 grams in carbohydrate.

The diabetes educator discussed with him how to best distribute his carbohydrates throughout the day and advised that he not skip meals. She also reviewed with him the best times to check his blood glucose and what the goals were for him.

After interpreting the CGM, his PCP decreased his Basaglar to 24 units and decreased his breakfast Humalog dose to 7 units. Other doses remained the same. He was instructed to check his blood glucose before meals and at bedtime and to call these results in one week to the diabetes educator.

Robert has subsequently decided to pursue CGM for personal use and is waiting to hear if his insurance company will authorize this for him.

Shared with permission
by Mary S. RN, CDE

Case Study 2

This case involves a 76-year-old man with type 2 diabetes of 10 years' duration. He takes extended-release glipizide, 5 mg in one pill daily; sitagliptin, 100 mg in one pill daily; and glargine insulin, 20 units subcutaneously at bedtime. He was checking blood glucose one or two times daily, usually in the morning, and all his SMBG results were within his target range.

However, his A1C was 9.0%, and the PCP had increased his basal insulin dose despite his objections that he was having frequent hypoglycemia and would wake up many times shaking in the middle of the night. The PCP felt that he could not be having significant hypoglycemia because there were no documented low SMBG results and his A1C was elevated at 9.0%.

He was referred for diabetes education and a 6-day blinded Professional CGM study. The CGM results indicated that his blood glucose levels were dropping by 200 mg/dl every night, and he was experiencing blood glucose levels < 70 mg/dl. The patterns also revealed lower morning glucose levels with sustained elevated blood glucose after meals throughout the day.

The CDE reviewed and discussed the CGM results with him. Because he was checking his blood glucose only in the morning, he was surprised by the pattern of elevation after meals, the rise of his glucose level throughout the day, and the significant drop in blood glucose values overnight related to his basal insulin and shown below.

After the CGM study, his basal insulin dose was decreased to 12 units and switched to mornings instead of bedtime, his glipizide was discontinued, and his sitagliptin was continued. He was started on 4 units of premeal rapid-acting insulin before supper because it is his biggest meal of the day, and he does not always eat breakfast or lunch.

After 3 months, he was free of hypoglycemia symptoms at night, and his A1C had dropped to 7.6%. He achieved his A1C target of < 8.0% (a less intense goal because of his history of comorbidities, including coronary heart disease and chronic kidney disease).
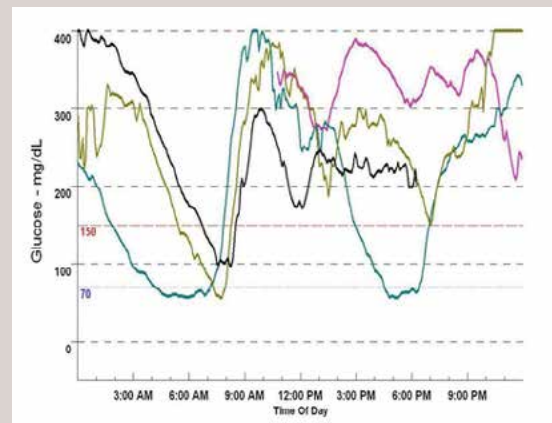
CGM trace. Nocturnal hypoglycemia and elevated glucose levels after meals were demonstrated on 4 days of CGM. Different colors represent different days.

-Excerpt from "Use of Continuous Glucose Monitoring as an Educational Tool in the Primary Care Setting" by A. Otavio Teodoro de Oliveira et al, Diabetes Spectrum, 2013.

Clinician Readiness to Promote CGM

How ready are you and your staff to promote Professional CGM in your practice? Tanenbaum et al., in 2018, surveyed 209 diabetes care providers who treat people with type 1 diabetes.

Three clinician personas emerged regarding readiness to promote continuous glucose monitoring.

- **Ready clinicians** *(20% of sample; 24% physicians, 38% certified diabetes educators – CDEs) had positive technology attitudes, had clinic time to work with people using CGM and found it easy to keep up with technology advances.*
- **Cautious clinicians** *(41% of sample; 17% physicians, 53% CDEs) perceived that their patients had many barriers to adopting CGM and had less time than the ready group to work with people using CGM data.*
- **Not yet ready clinicians** *(40% of sample; 9% physicians, 79% CDEs) had negative technology attitudes and the least clinic time to work with CGM data. They found it difficult to keep up with technology advances.*

Overcoming Therapeutic Inertia

Therapeutic inertia is a well-known problem in the management of diabetes. Treatment intensification may be delayed for a prolonged period due to several reasons. Kamlesh Khunti, FMedSci, FRCGP, FRCP, MD, PhD, presented an overview of the scope and im¬pact of therapeutic inertia as well as clinician barriers related to therapy intensification reported in the American Diabetes Association's publication, _Summary of the Proceedings of the American Diabetes Association Summit - Overcoming Therapeutic Inertia: Accelerating Diabetes Care FOR_LIFE._

These barriers include the following:
- lack of time
- lack of resources
- lack of training and education
- suboptimal patient medication-taking behavior
- perceptions about patients' ability and willingness to follow treatment protocols
- hypoglycemia concerns and management of comorbidities.

In this same publication, session participants were asked to share their ideas of the causes and impact of therapeutic inertia and to summarize that in one word. Words identified to describe the top contributors to therapeutic inertia were "time," "cost," "fear," "apathy" and "overwhelmed." Words identified to describe the solutions to address therapeutic inertia were "education" and "time."

A Professional CGM program can address therapeutic inertia by identifying glycemic patterns and changing the treatment plan to address problem areas that are uncovered. Changing the treatment plan does not only entail pharmaceutical intervention, but also, very importantly, includes an analysis of lifestyle factors and behavioral issues and a plan to overcome these obstacles. A diabetes educator is the best person on your team to address these topics with people with diabetes, as they are skilled at coaching persons with diabetes in all aspects of self-management of their condition using an evidence-based framework, the AADE7®Self-Care Behaviors.

Interpretation of CGM Data and Reports

The health care provider interprets the CGM reports retrospectively and evaluates for glycemic excursions above/below target range, seeking to identify patterns and potential causes for these excursions.

Device download reports vary by manufacturer and include differing data presentations; however, there has been a recent push to focus on use of the Ambulatory Glucose Profile (AGP), which was developed by the Park Nicollet International Diabetes Center (IDC) in Minneapolis, Minnesota. The use of one report would help to standardize care. The AGP includes summary statistics, a glucose profile graph and an insulin profile graph or glucose daily calendar graphs.

Example of AGP Report
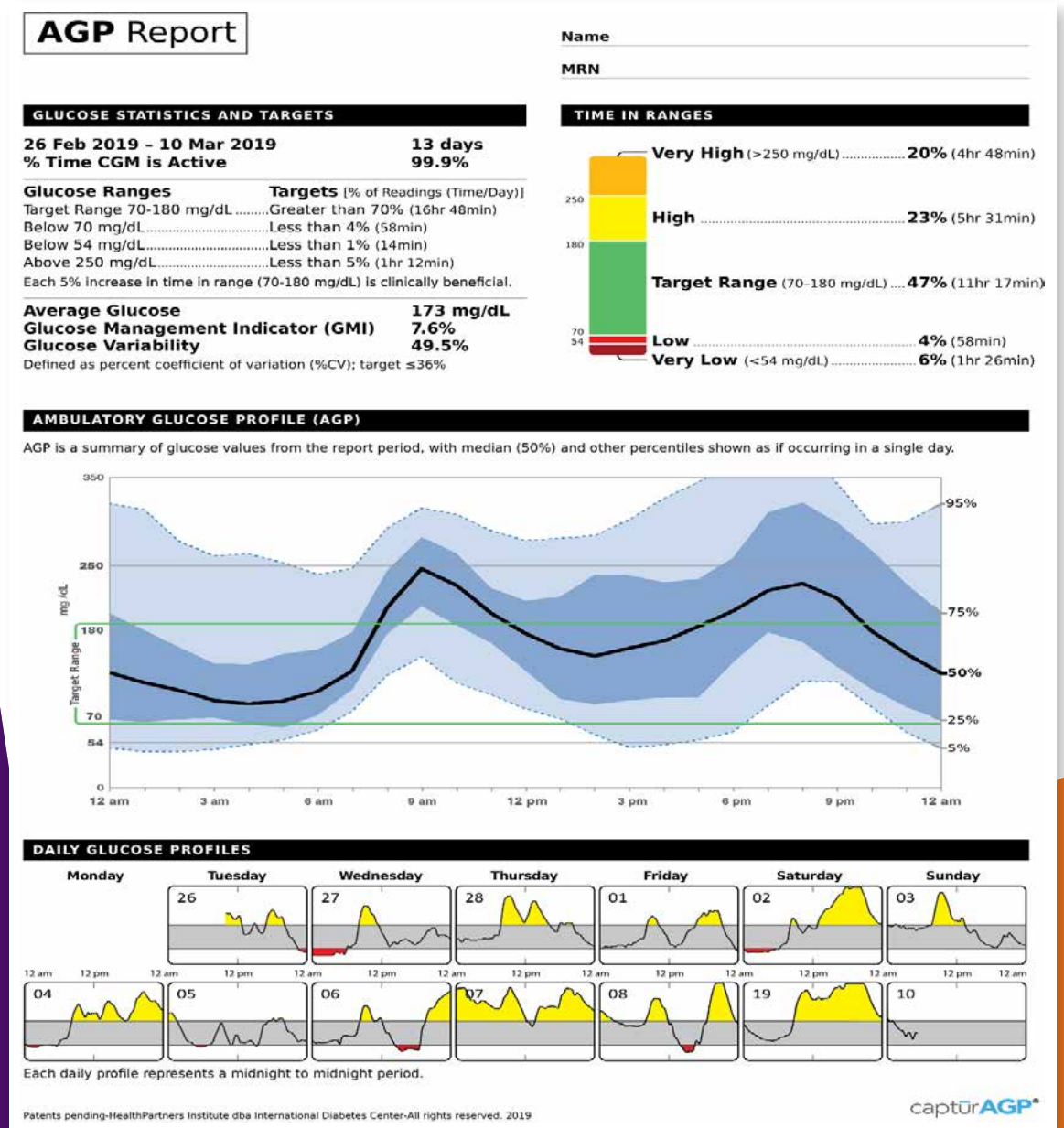
AGP Report from International Diabetes Center.

The 2017 International Consensus on Use of Continuous Glucose Monitoring report published in Diabetes Care provides a detailed description of the 14 key metrics that can be analyzed when reviewing retrospective data.

More recently (2019), the International Consensus on Time in Range identified standardized clinical targets for CGM data interpretation, as follows

Number of days CGM is worn 14 days is recommended
Percentage of time CGM is active 70% of data from 14 days is recommended
Mean glucose
Glucose Management Indicator (GMI) *This used to be called the estimated A1C (eA1C) but now uses an updated formula for converting CGM-derived mean glucose to an estimate of current A1C level.*
Coefficient of Variation (CV) *This is a measure of glycemic variability. A CV of less than or equal to 36% is considered acceptable, >36% is considered unstable and intervention is needed.*
Very High Time Above Range (TAR) % of readings and time >250 mg/dl
High Time Above Range (TAR) % of readings and time 181-250 mg/dl
Time In Range (TIR) % of readings and time 70-180 mg/dl
Low Time Below Range (TBR) % of readings and time 54-69 mg/dl
Very Low Time Below Range (TBR) % of readings and time <54 mg/dl

The first priority is to reduce the time spent below range (work to eliminate hypoglycemia) and then focus on decreasing time above range or increasing time in range.
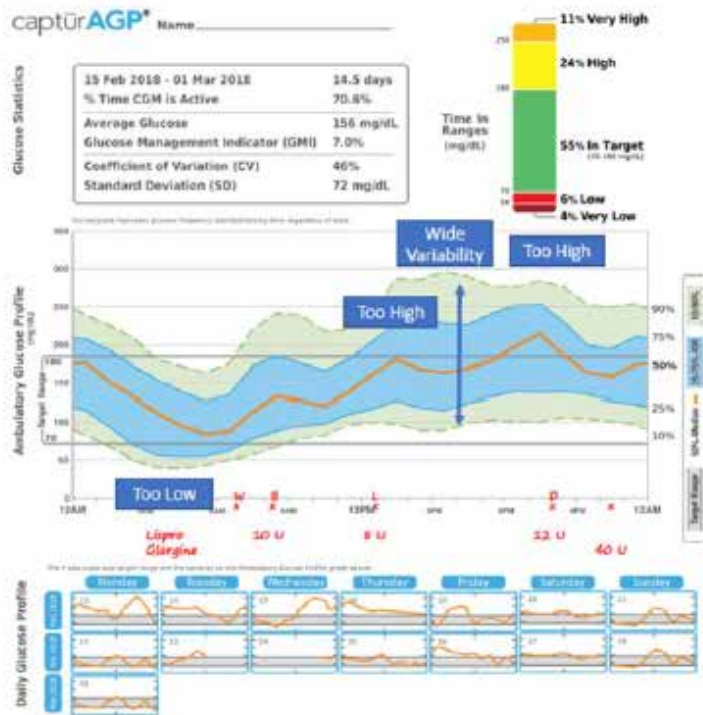
Glucose time in range (TIR) is another important measure and Dr. Richard Bergenstal, in 2018, identified correlations of TIR and HbA1C as follows:

Time in Range (TIR) %	Average HbA1C
40%	8.1%
50%	7.7%
60%	7.3%
70%	6.9%
80%	6.5%

Continuous Glucose Monitoring (CGM) Data Interpretation Using the Ambulatory Glucose Profile (AGP)[a]

Step 1 Confirm that adequate data are available. For Current CGM users, a minimum of 70% of 2 weeks of data is recommended.[3] Fewer days are needed when professional CGM systems are used.

Step 2 Print out the AGP and ask patients to describe their daily self-management. When are they taking their insulin and how much? When do they wake? When do they eat? Do they exercise and, if so, what type of exercise and when are they doing it? Document this information on the AGP printout.

Step 3 Ask the patients what they see in the AGP and why they think it may be important. Then listen. Interactive discussion with patients allows them to better understand how their insulin, food and other factors affect their glucose levels and also helps clinicians identify knowledge deficits or behaviors that may not support glycemic goals.

Step 4 Look for problematic glycemic patterns in the following order of priority:
1) Hypoglycemia, 2) Hyperglycemia, 3) Wide glycemic variability

Review the overall glucose profile (initial view) to determine the time of day when patterns are occurring, then review the daily graphs to double-check patterns to see if they are clustered on certain days.

Step 5 Encourage patients to reflect on what they think may be causing the problem and discuss potential solutions.

Step 6 Collaboratively develop an action plan. Make sure patients fully understand the changes they will be making and that they have the knowledge/skills to implement the plan.

Step 7 Make a copy of the marked up AGP printout for the patient and enter the original into the electronic medical record (EMR). If electronic entry is not possible, copy and paste the AGP into the EMR as a progress note.

[3]an expanded teaching tool is available at https://www.idcpublishing.com/.

Used with permission. Sage Publications. Reference Guide for Integrating Continuous Glucose Monitoring Into Clinical Practice.[11]

" I always assumed that Professional CGM was only helpful for someone on multiple insulin injections per day.

One of my patients on sulfonylurea medication came to me complaining of feeling sick every morning. Her recent HbA1C was 8.8% and her medication had been upwardly adjusted by another provider. She only checked her blood glucose once daily in the evening, due to difficulty affording the test strips, and her home results were in the 200 mg/dl range.

I decided to place a Professional CGM to see if it would uncover any useful information. When she came in for a return visit and her Professional CGM was downloaded, we reviewed it together. She was experiencing significant hypoglycemia overnight every night, with results dropping into the 50s mg/dl range. Due to "feeling sick" in the morning, she would consume a lot of carbohydrates throughout the day and would subsequently experience higher than target range glucose levels later in the day.

We changed her treatment plan and the hypoglycemia was eliminated and she felt much better. "

- Shared with permission Patricia S., Endocrinology CRNP

Professional CGM Program Implementation in Primary Care

Dr. Kathleen Eubanks-Meng is a primary care physician who implemented professional continuous glucose monitoring into her practice 18 months ago. "The process gets smoother over time." Her practice experienced some problems with the first device that they chose not being returned to the clinic. They have now switched to a disposable option which they have found makes for a smoother process. They do a prior authorization process and let the patient know what the cost may be. They have found that some people choose not to do the Professional CGM at the start of the year because they have not met their deductible yet. The practice keeps a recall list and checks with them again in 90 days.

Physicians order and interpret the Professional CGMs – the NP and PA can order and interpret as well. The CGM is placed by the tech or the LPN who also provides instruction on keeping the diary throughout the process. The individual is scheduled to wear the device for either 7 or 14 days. When they return, the same staff person that placed the CGM will remove it and download the device. The downloaded report is then sent to the ordering physician.*

The physicians were trained in CGM interpretation either by the device manufacturers or by on-line/live CME programs. They utilize a documentation template to report the findings and this is attached with an order set for patient instructions/disposition, which may include a visit to the clinic diabetes educator.

A follow up appointment is then scheduled in 5-7 days to meet with the physician and to go over the report. The billing for the entire process takes place after the interpretation is complete to ensure the loop is fully closed.

Dr. Eubanks-Meng reports, "The Professional CGM Program has been beneficial to both persons with diabetes and the healthcare providers." Her program is a revenue generator and has also improved the diabetes metrics within the practice.

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*An MD, NP, and PA are all qualified to interpret and act on CGM results.

Getting Started – Steps to Develop a Professional CGM Program

STEP

1. Identify the Need for Professional CGM Program

2. Establish the Clinical Team and Define Roles

3. Define Billing Process

4. Evaluate the Manufacturers and Determine Which Device(s) to Purchase

5. Contract with Manufacturer and Ongoing Inventory Management

6. Train the Staff

7. Design the Workflow

8. Prepare the Clinic/Team

9. Prepare the Person with Diabetes

10. Implement the Program

11. Evaluate the Program

12. Follow-Up/Plan for Future

STEP 1:
IDENTIFY THE NEED FOR
PROFESSIONAL CGM PROGRAM

Establish genuine need for your Professional CGM Program.

Begin by outlining benefits to the people with diabetes, providers and practice. What does your practice hope to gain by implementing this program? Will it solve current problems? Will it help improve the diabetes metrics in your practice? Are you doing all you can to reduce your patient's HbA1C levels and to optimize their management currently?

Once this genuine need is clearly identified, you will know that you are headed in the right direction.

Checklist of Items to Accomplish During this Phase

☐ Meet with administration and business leaders to discuss challenges and value of a Professional CGM Program

☐ Meet with the other providers or diabetes educators to identify current challenges with managing people with diabetes and opportunities to improve

☐ Meet with support staff to identify any concerns they have and obtain their buy-in

☐ Identify outcomes of a successful Professional CGM Program, both to people with diabetes and to the practice

QUICK TIP:

Reach out to colleagues at other practices with an already established Professional CGM Program and network with them about what worked – and what didn't go as smoothly as hoped – when getting the program off the ground. Continue to call on them and utilize them as a resource as you create and implement your program. The experience and advice of these key people will be invaluable to you as you move forward.

"Talent wins games, but teamwork and intelligence win championships."

- Michael Jordan

STEP 2:
ESTABLISH THE CLINICAL TEAM
AND DEFINE ROLES

Finding the right composition of the team is vital.

Enthusiastic and well-qualified team members will ensure a successful launch of the program. In this phase you will need to identify who will be on the team and what their roles will be. A diabetes educator/certified diabetes educator (CDE) is valuable to the team, if you have one on your staff. The diabetes educator can help the individual understand how various lifestyle factors and self-care behaviors affect their diabetes management.

Checklist of Items to Accomplish During this Phase

- [ ] Identify the members of your team

- [ ] Define roles and responsibilities of each team member

- [ ] Meet as a team regularly

- [ ] Seek ongoing feedback from all involved parties

QUICK TIP:

Anticipate barriers and be prepared to address them. Pay attention to the climate of the team. Seek ongoing ideas from all and don't be averse to changing direction if warranted. Actively seek to minimize disruption to current workflow.

STEP 3:
DEFINE BILLING PROCESS

Defining the billing process before you begin will help ensure that all potential roadblocks are anticipated, identified and addressed. Make a list of the common insurance payors that your patients may have. Investigate what their policies are surrounding Professional CGM use. Educate staff on the billing codes to utilize for Professional CGM.

Checklist of Items to Accomplish During this Phase

- [ ] Identify the team member to be accountable for coordination of insurance benefits and requirements

- [ ] Provide an in-service for staff on coding, billing and documentation requirements for Professional CGM

- [ ] Identify team member(s) to perform ongoing coding and billing audits of individuals in the program

Contact Insurance Company to Obtain Policy Regarding Professional CGM

↓

Find out if Prior Authorization is necessary

↓

Find out how often Professional CGM can be performed on same person

↓

Find out how to handle non-coverage or if not addressed in policy

↓

Create a letter of medical necessity template to be available as a resource

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QUICK TIP:

Mapping out the billing process before you begin will help prevent the delivery of non-covered services. Insurance rules get updated frequently, so you may need to reach out at least annually to determine if any new policies have been put into place surrounding Professional CGM.

Refer to table that appeared earlier in this Playbook, to evaluate the features of the various devices. All three manufacturers provide excellent resources and support for their products.

> Things to consider when making your choice of device:
>
> - **Care Between Use.** If you choose the Medtronic iPro2, you will need to have an area available for the cleaning and disinfecting of the transmitters, as well as staff available to perform this duty. The Abbott Freestyle Libre Pro and Dexcom G6 Pro are disposable so you will not need a cleaning station for them.
> - **Logging Other Events.** Event markers, such as exercise, food intake and medications taken, can be logged electronically through the Dexcom Studio and Medtronic iPro2 myLog app. When using the Abbott Freestyle Libre Pro, these events are logged on a paper diary and need to be compared side-by-side with the glucose data download.
> - **Length of Wear.** Determine if length of time for sensor wear is important. The Abbott Freestyle Libre Pro has the longest wear time, 14 days.
> - **Blinded or Unblinded.** Determine need for blinded versus unblinded device.
> - **Data/Reports.** Compare the download reports for ease of interpretation and completeness.

Checklist of Items to Accomplish During this Phase

☐ Meet with the manufacturer representatives for the devices that you are interested in

☐ Schedule vendor presentations of devices with members of your team

☐ Evaluate each vendor for information technology support, customer service and business processes

☐ Choose a vendor that will support you during the implementation period and beyond

QUICK TIP:

Consider testing all three devices to fully understand the processes involved surrounding each of them.

STEP 5:
CONTRACT WITH MANUFACTURER AND ONGOING INVENTORY MANAGEMENT

Once you have determined which device you will purchase and stock in your program, you will need to make a contract with the vendor. You will want to address customer service, IT support and other business needs.

For example, how many devices do you need? The Abbott Freestyle Libre Pro and Dexcom G6 Pro systems utilize disposable sensors and transmitters along with a multiple use reader. The Medtronic iPro2 utilizes disposable single use sensors along with a reusable transmitter. You want to ensure that your inventory items will not expire before they are used.

Checklist of Items to Accomplish During this Phase

☐ Determine where you will store your device components

☐ Identify team member responsible for inventory management and ensuring the device is cleaned and charged before being placed on another patient

☐ Does software need to be installed for downloading the device? Which computer(s) will you install it on? Do you need approval from your internal IT support?

☐ Place vendor contact information and customer support contact information in a prominent location for all staff to access as needed

☐ Estimate the budget required to obtain and maintain device components

☐ Outline clear and measurable goals for vendor contract. This will be very individual. The support needed (i.e., IT trouble shooting and other issues) is local and depends on the quality of the representative the company has in the area. Make a relationship with that person.

QUICK TIP:

Good vendor relations are an important piece of the success of your Professional CGM Program. Meet with your local representative at regularly scheduled intervals. Optimal inventory management will be a vital factor when calculating the ROI (return on investment) of your program.

STEP 6:
TRAIN THE STAFF

Staff will need to be trained on patient selection, use/ maintenance of the device, providing instructions to patient, diagnosis/coding/billing, documentation, interpretation and the process for dissemination of results to patient.

Checklist of Items to Accomplish During this Phase

☐ Develop protocol that lists characteristics that would make individuals most likely to benefit from Professional CGM

☐ Set up vendor training sessions for all involved staff

☐ Develop staff competencies, so their skills will be documented

☐ Set up provider training for diagnosis/coding/ billing, interpretation and documentation of download

☐ Start planning annual training refresher now

QUICK TIP:

Providing thorough pre-implementation training will help ensure a smooth start to the program. Solicit staff feedback frequently during and after the training sessions. Consider recording the training sessions so that new staff joining the program in the future will have access to it.

STEP 7:
DESIGN THE WORKFLOW

Adding a Professional CGM Program to your practice will require changes to your current workflow. You have already identified the roles of your team members, so you are aware of what new responsibilities they will be taking on. It is helpful to document the Professional CGM process from start to finish so you have a clear understanding of all steps.

Checklist of Items to Accomplish During this Phase

☐ Seek input from all team members regarding the design of the workflow

☐ Document visit from beginning to end

☐ Update existing protocols or document new ones to accommodate this new workflow in daily practice

☐ Plan for enhanced staffing levels as you roll out the new program

☐ Provide support and resources surrounding the new workflow

☐ Solicit staff feedback every step of the way

☐ Plan for ongoing scheduled evaluation of workflow

☐ Determine what data you will want to collect ongoing

QUICK TIP:

It is important to consider all perspectives when designing the workflow, including that of the person with diabetes, the support staff and the providers. You may want to appoint a patient representative to assist with design, implementation and evaluation of the workflow to ensure that you fully understand their perspective. As you learn and grow, your program will continue to adjust its workflow.

STEP 8:
PREPARE THE CLINIC/TEAM

Ensure that all team members are aware of their roles and responsibilities. Proper staff preparation will make sure that the team is on board with the plan and motivated to put in their best effort to help make it a success. Remember to start process evaluation as soon as the implementation stage kicks off.

Checklist of Items to Accomplish During this Phase

- ☐ Host a program launch kick-off event and review roles/responsibilities

- ☐ Identify staff "superusers" who can serve as resources to others

- ☐ Have vendor and IT available during implementation

- ☐ Make device procedure reference materials and troubleshooting guides widely available

- ☐ Provide a forum for staff to provide feedback and suggestions

QUICK TIP:

Keep an open communication line with the team members and involved staff. It is important that the team feels that this is a collective effort and that everyone's feedback is equally important.

"Management is doing things right; leadership is doing the right things."

– Peter F. Drucker

STEP 9:
PREPARE THE PERSON WITH DIABETES

The Professional CGM Program will require frequent and active input from the person with diabetes. It is vitally important to hold a conversation with them that provides education for them about the importance of tracking food intake, exercise and diabetes medication timing. They need to know that the interpretation of the results requires these inputs for best comprehension.

Checklist of Items to Accomplish During this Phase

☐ Develop a handout which discusses the benefits of Professional CGM and the importance of keeping a log of food intake, activity and diabetes medication

☐ Check insurance benefits for Professional CGM. Complete prior authorization with insurance company if needed. Write letter of medical necessity if needed. Most insurance, including Medicare and Medicaid, will cover Professional CGM 2x year – but this number should be known and verified.

☐ Have person sign consent form for insertion of sensor if needed

☐ Schedule return appointment for patient to return the sensor and review interpretation with provider. Many individuals will mail back their sensor. Some providers will provide their interpretations via telephone.

QUICK TIP:

Make the person with diabetes the centerpiece of the program. Remember that the most prepared person will yield the best interpretation of the data. Spend time up front on education and support to ensure their understanding of the process and goals of the program.

STEP 10:
IMPLEMENT THE PROGRAM

You are now ready to try out your new program! All the pieces should be in place. Stress the importance of educating and preparing the patient with the team. Solicit feedback and ideas from staff and patients throughout the implementation process. Start tracking success measures at program initiation.

Checklist of Items to Accomplish During this Phase

☐ Provide on-site technical and product support resources to staff during launch

☐ Perform frequent check-ins with staff at this beginning phase of the program implementation

☐ Schedule a weekly staff meeting to discuss how things are going

☐ Start collecting any data that you will want to analyze ongoing now

☐ Walk through the process from start to finish

QUICK TIP:

If possible, try to have some cushion in your staffing during this time. This will enable staff to take the time necessary to fully learn and practice the new procedures and processes. Communicate frequently with your support staff to identify any challenges or obstacles to program success. Utilize vendor support and IT support to ensure a smooth implementation.

STEP 11:
EVALUATE THE PROGRAM

Program evaluation is an ongoing process. Refer often to the metrics of program success that you have identified. Celebrate once you are meeting these success points. If you are not meeting them, determine what the obstacles and challenges are. Practice continuous quality improvement. Be thoughtfully and quickly responsive to suggestions/ideas/feedback.

Checklist of Items to Accomplish During this Phase

☐ Compile and sort staff feedback

☐ Analyze and evaluate the data that you have collected

☐ Compare diabetes outcome post-Professional CGM Program to pre-program outcomes

☐ If you are not meeting success metrics, re-evaluate your program process and amend as necessary

☐ If you are meeting success metrics, disseminate the results widely

☐ Meet with the entire team to determine next steps. Is program the right size? Does it have the right composition of staff? Is the device inventory satisfactory?

QUICK TIP:

Establish a timeline for ongoing program evaluation. A program may not attain the expected measures of success in the first few rounds of evaluation. Staff will become more efficient with the program processes as time goes by. Ease of use will improve, and staff confidence and competence will show ongoing improvements as well.

STEP 12:
FOLLOW-UP/PLAN FOR FUTURE

Planning for the future of your Professional CGM program is a crucial component of a successful program. What are the next steps for your program? Do you want to establish a satellite location? Do you want to start incorporating personal CGM into your practice? Do you want to start working with patients remotely? Do you want to offer an additional CGM product in your program?

Checklist of Items to Accomplish During this Phase

- ☐ Hold a meeting with the entire team to discuss future goals for the program

- ☐ Explore feasibility of goals

QUICK TIP:

Remember to include administration when planning for the future of the program.

PART THREE:
Worksheet
Resources

The following resources have
been developed to enhance your
program design, implementation
and evaluation as detailed
in the Playbook.

"Alone we can do so little; together we can do so much."

-Helen Keller

Worksheet 1:
Evaluate the Value (Pros) and Challenges (Cons)
of Professional CGM Program

PROS	CONS

Some examples of pros:
Improve self-care outcomes, improve diabetes metrics, create a revenue stream.

Some examples of cons:
Increased workload to staff, pushback from providers,
need for dedicated space for the program, etc.

Worksheet 2:
Identify Outcomes of a Successful
Professional CGM Program

List the criteria for your program success. Examples may be improved self-care outcomes (be specific about your population), meet diabetes care metrics, create a new revenue source, etc.

Place this list in a prominent location to allow for frequent review.

Worksheet 3:
Form Your Team

How many teams do you need?

Often there will be several sub-teams: A Leadership Team that makes high level decisions, a Management Team that is accountable for day-to-day operations and an Advisory Team that may be partly composed of customers.

List your team structure and team members below:

LEADERSHIP TEAM

MANAGEMENT TEAM

ADVISORY TEAM

_____

_____

_____

_____

_____

_____

_____

_____

Leadership Team:
- Identify need for the project
- Provide administrative support for the project
- Identify key members of management team
- Market the project
- Vendor contracting and relations
- Define and evaluate success

Management Team:
- Responsible for day-to-day operations
- Identify team members and roles
- Implement program
- Provide ongoing support to team members
- Evaluate program continuously

Advisory Team:
- Identify need for the project
- Partner with the patient and evaluate patient satisfaction with program
- Participate with program implementation and evaluation

Worksheet 5:
Identify Program Processes and
Assign Tasks to Team Members

Examples:

Program Processes/Tasks	Team Member Assigned
Billing/Prior Authorization/Pre-certification	
Inventory Management	
Placement of Device	
Patient Instruction	
Download of Device Data	
Cleaning of Device (if applicable)	
Interpretation of Device Data	
Communication of Plan to Patient	
Analyze Outcomes Data	
Market the Program	

Worksheet 6:
Billing and Coding

CPT Codes for Placement and Interpretation of Professional CGM		
CPT Code	**Explanation of Code**	**Who Can Perform Duty**
95250	This code is used both for the placement of Professional CGM and the downloading of the data. Placement can be performed by multidisciplinary health care providers, as long as it is within their scope of practice. This code should only be reported once per month per patient, although this may vary by payer.	Examples of staff who may perform this duty include: MD/DO, NP/PA, CDE, RD, RN
95251	This code is used for interpretation of Professional CGM. Does not require a face-to-face visit.	Interpretation can be performed by MD/DO or NP/PA

Notes:
- Both codes may only be used if the patient wears the device for a minimum of 72 hours.
- Both codes may only be reported once per month per patient, although this may vary by payer.
- An E/M Code (Evaluation and Management) can be billed on the same day of either of these codes as long as a distinct and separate E/M service was medically necessary and provided over and above the Professional CGM service. In this case, the modifier -25 must be attached to the E/M code.
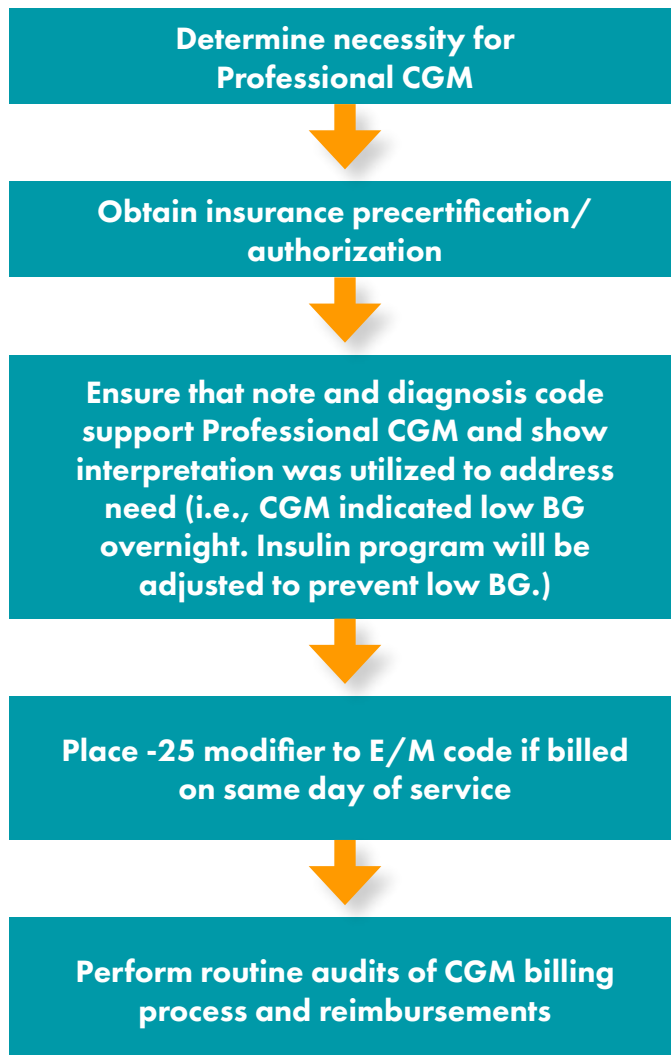
Checklist for payors:

☐ Do they have a formal policy for Professional CGM?

☐ Do they require prior authorization?

☐ How often do they allow Professional CGM to be performed on a particular patient?

Worksheet 6:
Billing and Coding (continued)

Flowchart of billing and coding process

> **Determine necessity for Professional CGM**
>
> ⬇
>
> **Obtain insurance precertification/ authorization**
>
> ⬇
>
> **Ensure that note and diagnosis code support Professional CGM and show interpretation was utilized to address need (i.e., CGM indicated low BG overnight. Insulin program will be adjusted to prevent low BG.)**
>
> ⬇
>
> **Place -25 modifier to E/M code if billed on same day of service**
>
> ⬇
>
> **Perform routine audits of CGM billing process and reimbursements**

Items to document in the interpretation note:
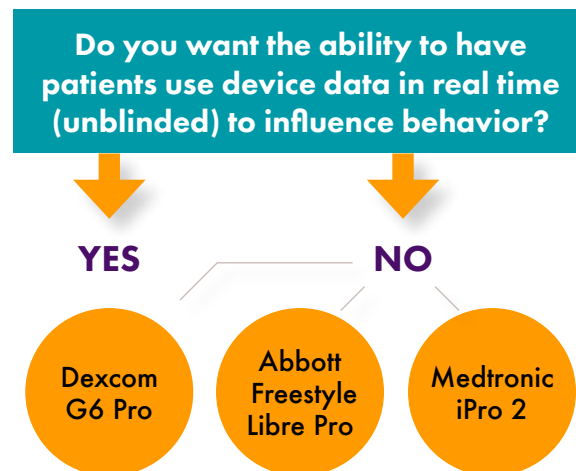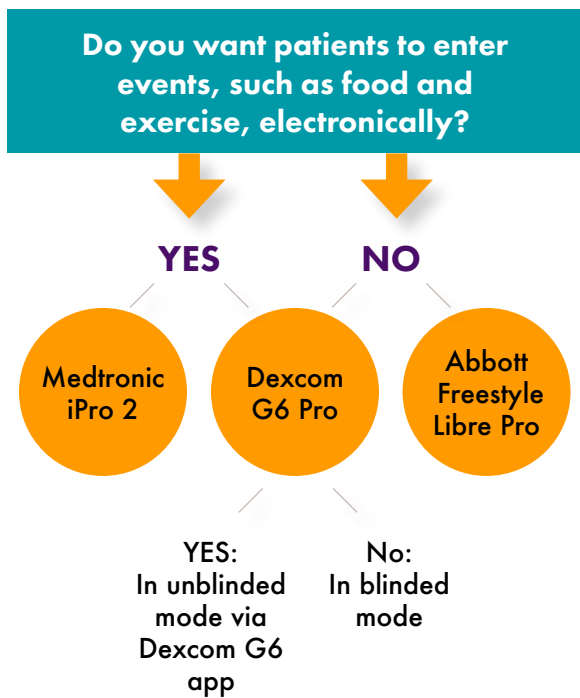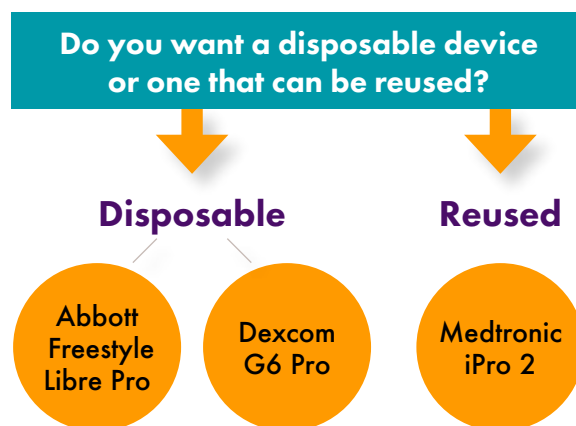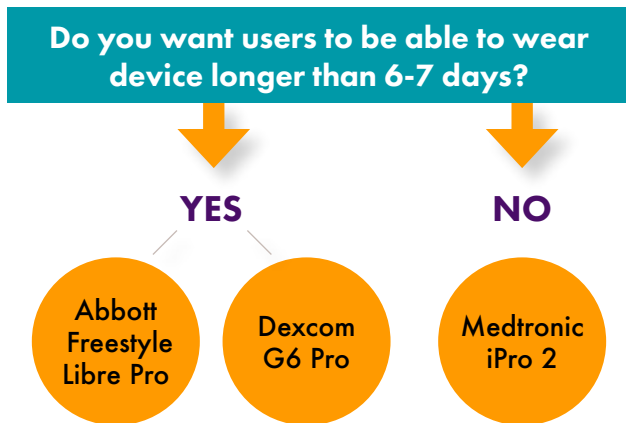(you can amend this note content as needed by your practice)

- Duration that the patient wore the Professional CGM device (needs to be >72 hours)
- Current diabetes treatment plan
- Current HbA1C
- Time in target range, time above and below target range

- Patterns of hypo/hyperglycemia
- Any changes recommended to treatment plan
- Any further actions, such as referral to diabetes educator
- Copy of the device download

Worksheet 7:
Device Choice Algorithm

Features	Abbott Freestyle Libre Pro	Dexcom G6 Pro	Medtronic iPro2
Blinded or Unblinded	Blinded	Either	Blinded
Wear Time	14 days	10 days	6 days
Calibration Required?	0	0	3-4 times daily
Components	Disposable combined glucose sensor/transmitter Separate touchscreen reader device	Disposable wired sensor/transmitter Separate touchscreen reader device that does not go home with the person with diabetes	Disposable wired sensor Data transmitter attached to the sensor
Care Between Use	Disposable sensor/transmitter	Disposable sensor/transmitter	Transmitter must be cleaned and disinfected
Insertion	Single step process with auto-inserter	Two-step process which includes inserting sensor and attaching transmitter	Multi-step process which includes inserting and taping both the sensor and transmitter
Site	Upper Arm	Abdomen	Abdomen
Downloading/Data Reports	LibreView	CLARITY	Carelink

Continued next page

Worksheet 7:
Device Choice Algorithm (continued)

Do you want users to be able to wear device longer than 6-7 days?

YES → Abbott Freestyle Libre Pro | Dexcom G6 Pro

NO → Medtronic iPro 2

Do you want a disposable device or one that can be reused?

Disposable → Abbott Freestyle Libre Pro | Dexcom G6 Pro

Reused → Medtronic iPro 2

Do you want patients to enter events, such as food and exercise, electronically?

YES → Medtronic iPro 2 | Dexcom G6 Pro

NO → Abbott Freestyle Libre Pro

YES: In unblinded mode via Dexcom G6 app

No: In blinded mode

Do you want the ability to have patients use device data in real time (unblinded) to influence behavior?

YES → Dexcom G6 Pro

NO → Abbott Freestyle Libre Pro | Medtronic iPro 2

Disposable Devices:
- Order enough so you don't run out
- Monitor use and order when XX are left. You will be able to soon figure out how many devices are used per month in each program site and keep a month's supply on hand. You can then order when you get to this number, so you will always have a supply.
- Monitor expiration dates and store product that is expiring sooner in the front
- Make sure there are enough paper logs available to distribute to every patient
- Place a couple of device readers in the clinical area and have some back-ups

Reusable Devices:
- Order enough devices to have on hand
- Monitor warranty periods for the transmitters and order new units before the current ones fall outside of warranty period
- Track devices to ensure that they are returned by the patient in a timely fashion
- Consider having patient sign a contract that they promise to return the transmitter to clinic
- Set up an area in clinic for cleaning and disinfecting the transmitter
- Ensure that staff is following the procedure for cleaning and disinfecting

Consider Ordering CGM in the Following Situations:

- HbA1C greater than 9.0 %
- Discordant HbA1C and fingerstick glucose data
- Change in diabetes treatment plan
- Patient has renal impairment
- Patient with frequent hypoglycemia or hypoglycemia unawareness
- Patient with gastroparesis
- Patient does not follow recommendations for checking fingerstick glucose levels
- Annually on patient that is being treated with intensive insulin management plan
- When data are needed to determine Time in Range (TIR)

HbA1C data are collected prior to placement of Professional CGM and again 3 months later

Sample Documentation

Used by permission, Diana Isaacs, PharmD, BCPS, BC-ADM, Cleveland Clinic.
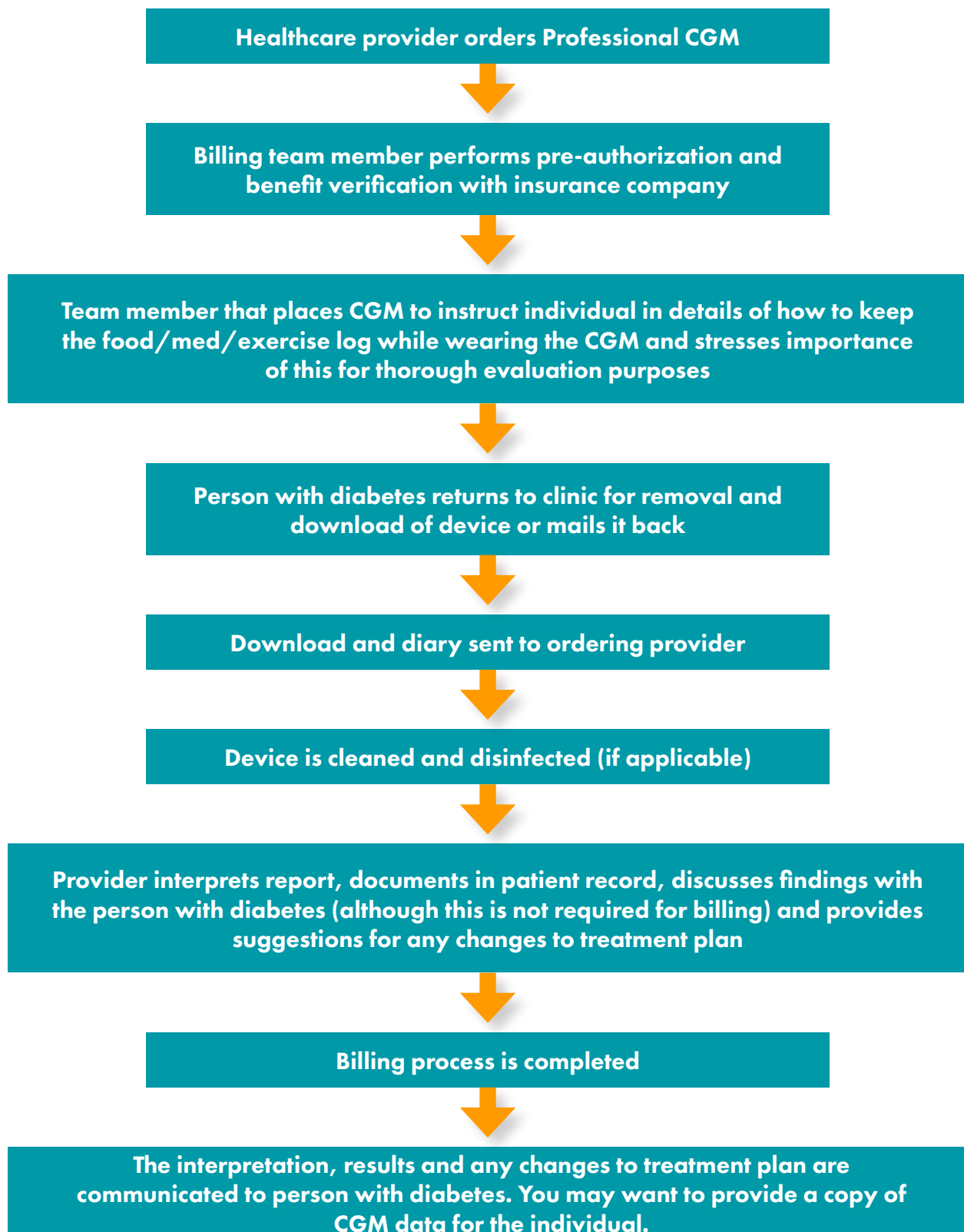
Documentation

Summary of Professional CGM Findings

1. Average glucose is 148mg/dL +/-48   BG range: 68-313
2. Total frequency of hypoglycemia: overall 0% BG<70, lowest BG of 68 occurred one time at 7pm
3. Nocturnal hypoglycemia was NOT noted
4. Hyperglycemia episodes: 22% BG>180, post-prandial, often d/t missing prandial insulin, injecting prandial insulin late, or eating high CHO with limited protein.
5. The patient was afraid to inject lispro if BG was in range before meal

Lifestyle and Personalized Self-Management Education

+++INCLUDE AGP or CGM summary with documentation

Worksheet 10:
Professional CGM Process Flow

Healthcare provider orders Professional CGM

↓

Billing team member performs pre-authorization and benefit verification with insurance company

↓

Team member that places CGM to instruct individual in details of how to keep the food/med/exercise log while wearing the CGM and stresses importance of this for thorough evaluation purposes

↓

Person with diabetes returns to clinic for removal and download of device or mails it back

↓

Download and diary sent to ordering provider

↓

Device is cleaned and disinfected (if applicable)

↓

Provider interprets report, documents in patient record, discusses findings with the person with diabetes (although this is not required for billing) and provides suggestions for any changes to treatment plan

↓

Billing process is completed

↓

The interpretation, results and any changes to treatment plan are communicated to person with diabetes. You may want to provide a copy of CGM data for the individual.

Worksheet 11:
Sample Instructions for Professional CGM
for the Person with Diabetes

The purpose of the Professional Continuous Glucose Monitor (CGM) is to assess your blood sugar patterns in response to what you eat, the diabetes medications you take and physical activity. This is why we have you keep a diary of what you eat and when, what time you take your diabetes medications and what activity you do and when, while you are wearing the continuous glucose monitor.

- The continuous glucose monitoring (CGM) device will monitor your blood sugar frequently throughout the day and night.
- Please be sure to record everything that you eat, including portion sizes, all activity you do and when you take your diabetes medication.
- It is okay for you to shower and go about your normal daily activities while wearing the device.
- It is best to wear the device when you are having a normal week and best to avoid if you will be on vacation or undergoing medical testing or procedures.
- At your next scheduled appointment your continuous glucose monitor will be removed, and the data will be evaluated by your health care provider. We will contact you about those results and provide you with next steps, or you may be provided with the option to mail in or drop off your continuous glucose monitor to the clinic.
- If the device falls off before your next appointment is scheduled, simply return the device and your diary to the clinic. If it has been on for greater than three days there might be enough data to complete the test. If it is less than three days, you may need to have another device placed.

Sample Professional CGM Downloads from Each Manufacturer

"I am not sure how I practiced without CGM."

- endocrinology provider

Abbott Freestyle Libre Pro

Dexcom G6 Pro

Medtronic iPro2

Case Study

Patient Profile

Sex/Age: Male, 59 years old

Disease diagnosis: Type 2

HbA1c: 7.9%

Diabetes medication profile: Bi-phasic insulin aspart twice daily, 27 units 07:00 and 19 units at 21:00

Current glucose monitoring: Pre-breakfast, pre-evening meal and occasionally at other times of the day

Rationale for sensor monitoring: Patient has a busy lifestyle which makes regular SMBG testing difficult, particularly when at work; however, he has experienced the "odd" unexpected high reading and would like to know more about what the cause might be.

Baseline Report - Daily Patterns

Glucose Pattern Insights

17 September 2013 - 30 September 2013 (14 days)

LOW-GLUCOSE ALLOWANCE SETTING: Medium
MEDIAN GOAL SETTING: 140 mg/dL (A1c: 6.5% or 48 mmol/mol)

Estimated A1c **7.6% or 60 mmol/mol**
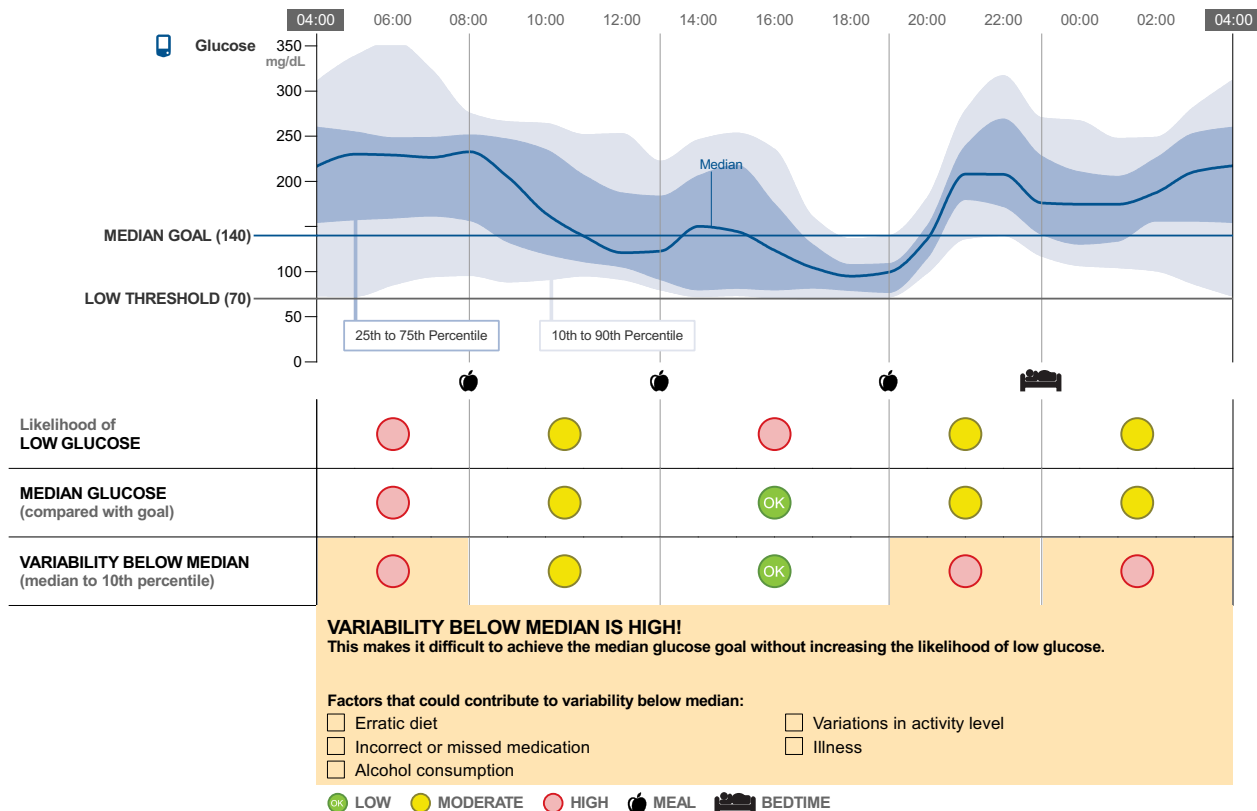
| | 04:00 | 06:00 | 08:00 | 10:00 | 12:00 | 14:00 | 16:00 | 18:00 | 20:00 | 22:00 | 00:00 | 02:00 | 04:00 |

25th to 75th Percentile
10th to 90th Percentile
Median
MEDIAN GOAL (140)
LOW THRESHOLD (70)

Likelihood of **LOW GLUCOSE**	HIGH	MODERATE	HIGH	MODERATE	MODERATE
MEDIAN GLUCOSE (compared with goal)	HIGH	MODERATE	OK	MODERATE	MODERATE
VARIABILITY BELOW MEDIAN (median to 10th percentile)	HIGH	MODERATE	OK	HIGH	HIGH

VARIABILITY BELOW MEDIAN IS HIGH!
This makes it difficult to achieve the median glucose goal without increasing the likelihood of low glucose.

Factors that could contribute to variability below median:
- ☐ Erratic diet
- ☐ Incorrect or missed medication
- ☐ Alcohol consumption
- ☐ Variations in activity level
- ☐ Illness

OK LOW MODERATE HIGH MEAL BEDTIME

Abbott

Insights

1. **Are the readings within target range (identified target range is 70 – 150mg/dL)?** Very few readings are within the range, the majority are above it.

2. **What are the patterns of hypoglycemia?** There is tendency towards hypoglycemia from waking and particularly during the afternoon to early evening.

3. **What is the shape of the median curve?** The median curve falls sharply from 08:00 followed by a downward trend with some fluctuations until early evening when it rises sharply before plateauing until 20:00.

4. **What is the width of the IQR?** The IQR is generally wide, particularly overnight.

5. **Where is the risk of hypoglycemia the greatest as indicated by the "likelihood of low glucose" assessment?** The risk of overnight hypoglycemia and the time between 12:00-18:00 is of greatest concern.

6. **Where is the highest deviation from the median glucose goal indicating the need for greater clinical attention?** This occurs between 04:00 and 08:00 where the risk is high. Clinical attention should be focused on this period of the day in order to improve and meet HbA1c targets.

7. **Where is the variability below the median greater than a level that would support achieving the median goal without potentially causing low blood glucose?** The variability below the median is high from 19:00-08:00. This places the patient at high moderate –high risk of hypoglycemia if factors affecting this variability are not identified and corrected prior to making medication adjustments.

Actionable Insights

	Considerations	Next Steps
Target Range	• Despite a reasonable HbA1c, only some day time values are within range. • How often is glucose testing completed during the late afternoon, pre-dinner or at bedtime? • What changes does he make as the result of high glucose test results • How often are insulin injections missed or delayed and taken after a meal? • What concerns or fears does he voice regarding the potential for hypoglycemia during the night?	• Review food record keeping and refer to dietitian for food choices and portion sizes and meal pattern. • Observe patient demonstrating pen preparation and injection technique, including correct suspension of the insulin. • Discuss any concerns regarding glucose control.
Patterns of Hypoglycemia	• What consistent increase in physical activity is occurring midday that is resulting in lower glucose levels in the later afternoon • How often does insulin stacking occur? • Does he inconsistently change the dose of insulin prescribed in response to a high glucose test result? • What concerns or fears does he voice regarding the potential for hypoglycemia during the night? • What steps are consistently being taken to avoid hypo events overnight that may be contributing too much higher values during the night and upon waking?	• Discuss possible causes of variability – including exercise, alcohol, lifestyle, meal pattern. • Evaluate his ability to recognize hypoglycemia • Review prevention and appropriate treatment of hypoglycemia.
Shape of Median Curve	• What type of food choices or other factors are impacting the erratic pattern of the median curve? • What steps are taken to avoid or treat low glucose values? • How often is extra insulin taken to correct high glucose levels? • Does the patient properly suspend the pre-mixed insulin prior to placing it in syringe and injecting?	• Review food records, insulin doses and technique. • Re-emphasize the need for consistent dosing and timing of insulin injections. • Discourage insulin stacking as the result of a high glucose test result.
Width of IQR	• What actions are being taken or what food is being consumed that is leading to the pronounced overnight variability?	• Education and discussion regarding the impact of food and lifestyle choices on glucose control. • Discuss appropriateness of the current insulin regimen relationship to suiting the patient's lifestyle. • Consider insulin pump therapy or multiple daily injections if the current insulin therapy does not meet his lifestyle.

3 of 3

Abbott

Pro
Session 1 | Fri Feb 14, 2020 - Mon Feb 24, 2020

Glucose

Average Glucose

158 mg/dL

Standard Deviation

61 mg/dL

Coefficient Of Variation

38%

Time in Range

8% Very High
20% High
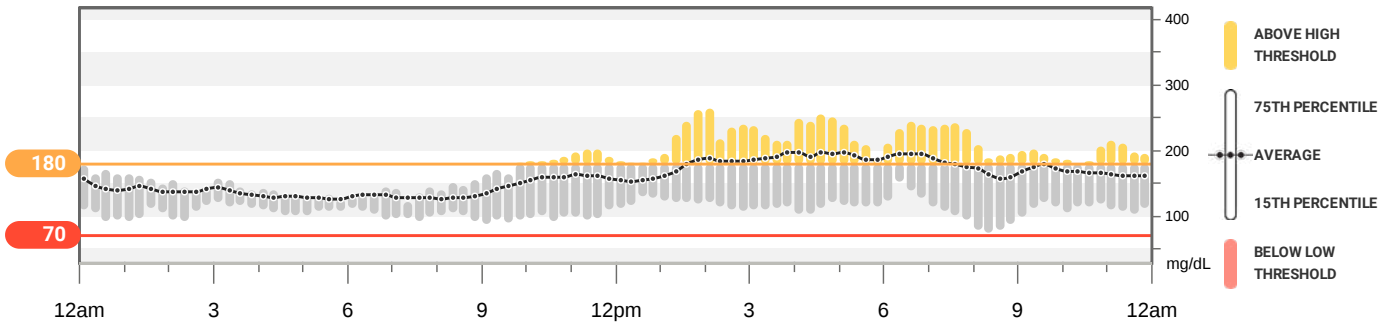**71% In Range**
<1% Low
0% Very Low
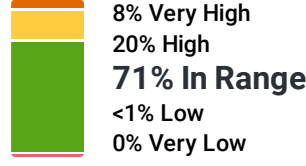
Target Range: 70-180 mg/dL

Sensor Usage
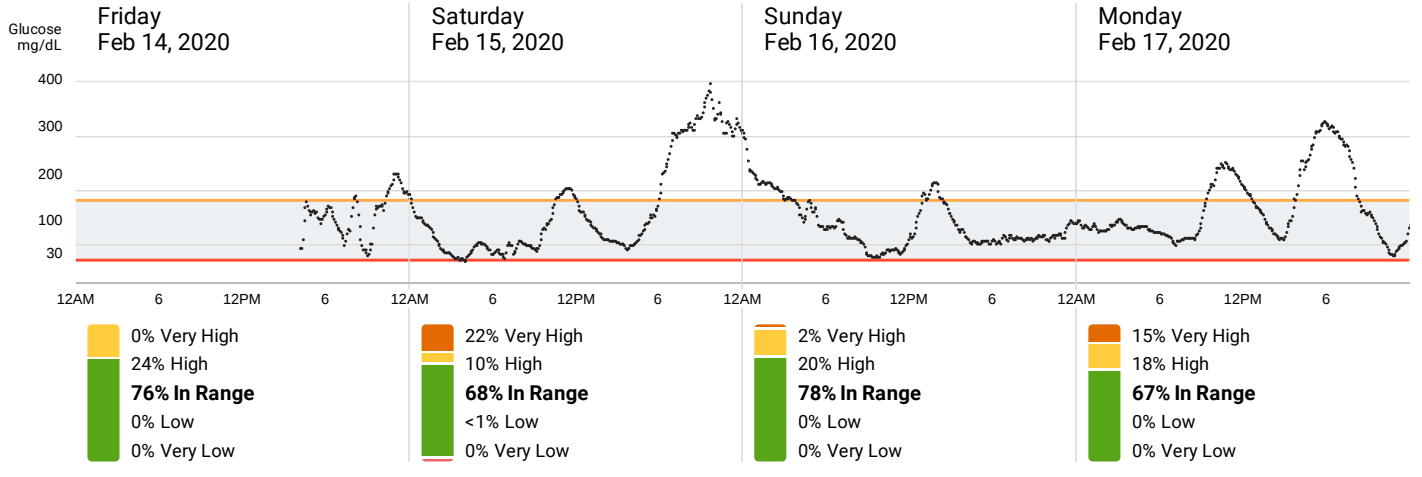Days with CGM data
100%
10/10

Pro Session Trends

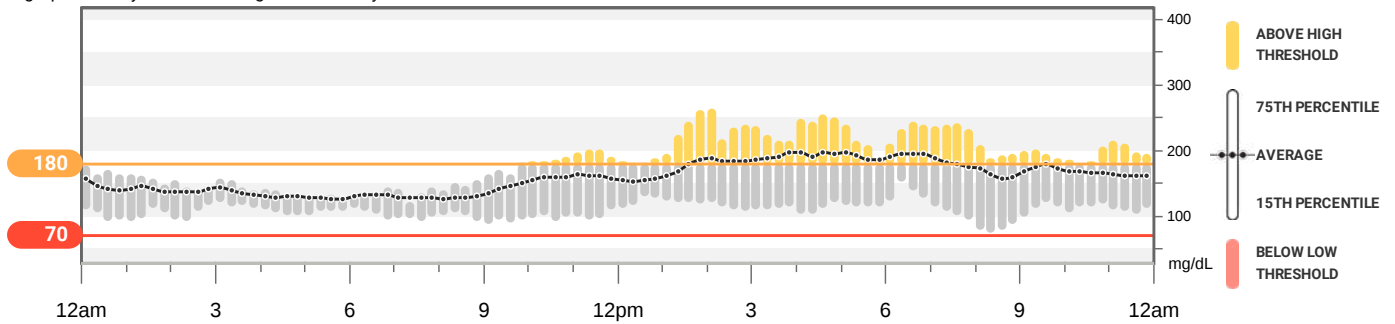|	
ABOVE HIGH THRESHOLD	
75TH PERCENTILE	
AVERAGE	
15TH PERCENTILE	
BELOW LOW THRESHOLD	

Patterns

1 **Patient's best glucose day was February 19, 2020**
Patient's glucose data was in the target range about 91% of the day.

Pro
Session 1 | Fri Feb 14, 2020 - Mon Feb 24, 2020

Dexcom CLARITY

Friday
Feb 14, 2020

- 0% Very High
- 24% High
- **76% In Range**
- 0% Low
- 0% Very Low

Saturday
Feb 15, 2020

- 22% Very High
- 10% High
- **68% In Range**
- <1% Low
- 0% Very Low

Sunday
Feb 16, 2020

- 2% Very High
- 20% High
- **78% In Range**
- 0% Low
- 0% Very Low

Monday
Feb 17, 2020

- 15% Very High
- 18% High
- **67% In Range**
- 0% Low
- 0% Very Low

Tuesday
Feb 18, 2020

- <1% Very High
- 42% High
- **57% In Range**
- 0% Low
- 0% Very Low

Wednesday
Feb 19, 2020

- 0% Very High
- 9% High
- **91% In Range**
- 0% Low
- 0% Very Low

Thursday
Feb 20, 2020

- 21% Very High
- 7% High
- **70% In Range**
- 2% Low
- 0% Very Low

Friday
Feb 21, 2020

- 15% Very High
- 17% High
- **64% In Range**
- 4% Low
- 0% Very Low

Saturday
Feb 22, 2020

- 0% Very High
- 31% High
- **69% In Range**
- 0% Low
- 0% Very Low

Sunday
Feb 23, 2020

- 0% Very High
- 23% High
- **77% In Range**
- 0% Low
- 0% Very Low

Monday
Feb 24, 2020

- 4% Very High
- 32% High
- **64% In Range**
- 0% Low
- 0% Very Low

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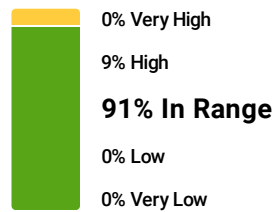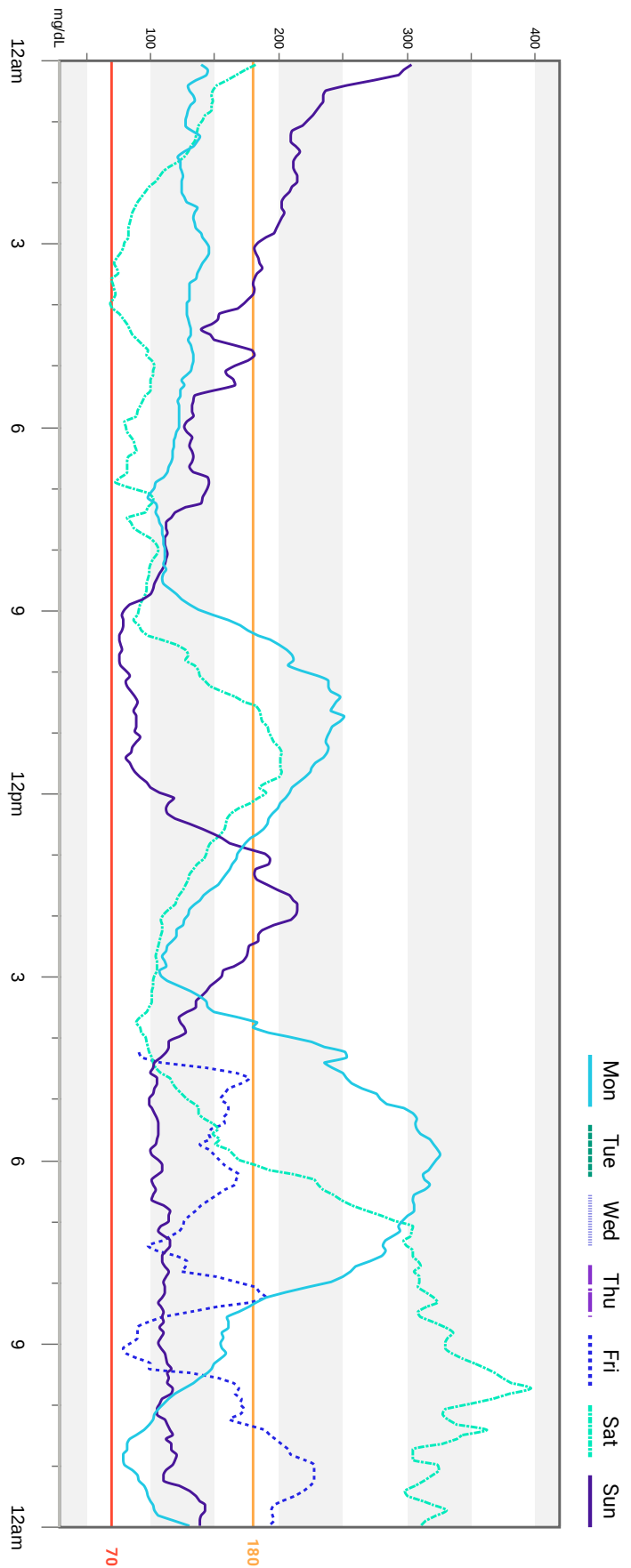
Overview

11 days | Fri Feb 14, 2020 - Mon Feb 24, 2020

Patient a02 G6 Pro | ID: don't delete | DOB: Jan 1, 2001

dexcom CLARITY

Glucose

Average Glucose

158 mg/dL

Standard Deviation

61 mg/dL

GMI

N/A

Time in Range

8% Very High
20% High
71% In Range
<1% Low
0% Very Low
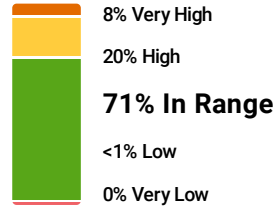
Target Range: 70-180 mg/dL

Sensor Usage

Days with CGM data

91%

10/11

Avg. calibrations per day

0.0

Top Patterns

1 Patient's best glucose day was February 19, 2020
Patient's glucose data was in the target range about 91% of the day.

This graph shows your data averaged over 11 days

ABOVE HIGH THRESHOLD
75TH PERCENTILE
AVERAGE
15TH PERCENTILE
BELOW LOW THRESHOLD

12am 3 6 9 12pm 3 6 9 12am

Generated at: Mon, Jul 6, 2020 4:10 PM PDT

Overview
11 days | Fri Feb 14, 2020 - Mon Feb 24, 2020

Devices

Dexcom G6 Pro

CGM ID

Serial Number	**PL64501792**
Uploaded On	**February 28, 2020**
Model	**G6 Pro**

Patterns

11 days | Fri Feb 14, 2020 - Mon Feb 24, 2020

1 **Patient's best glucose day was February 19, 2020**

Patient's glucose data was in the target range about 91% of the day.

Wed, Feb 19, 2020
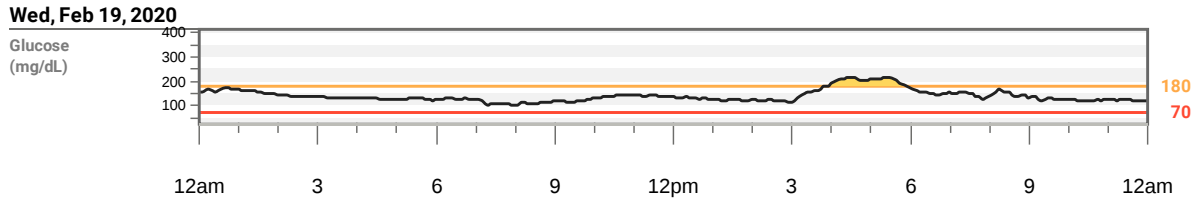
Glucose (mg/dL)

Statistics for this day

Average Glucose

141 mg/dL

Standard Deviation

25 mg/dL

Time in Range

0% Very High

9% High

91% In Range

0% Low

0% Very Low

Target Range: 70-180 mg/dL

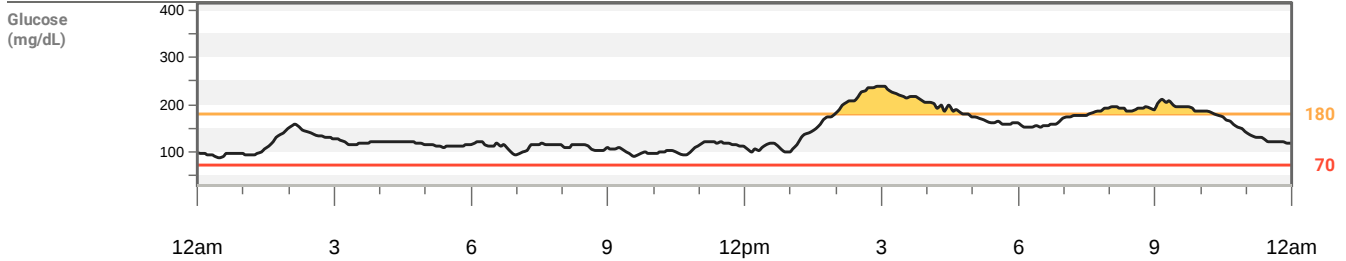**Legend**

CALIBRATIONS

CARBS

HEALTH

FAST-ACTING INSULIN / INSULIN

LONG-ACTING INSULIN

ALERTS

EXERCISE

MULTIPLE EVENTS

Overlay

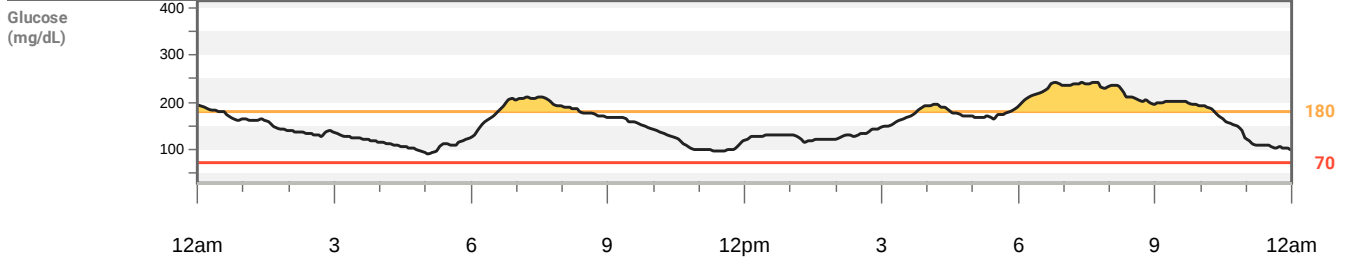**11 days** | Fri Feb 14, 2020 - Mon Feb 24, 2020
Week 2 | Tue Feb 18, 2020 - Mon Feb 24, 2020
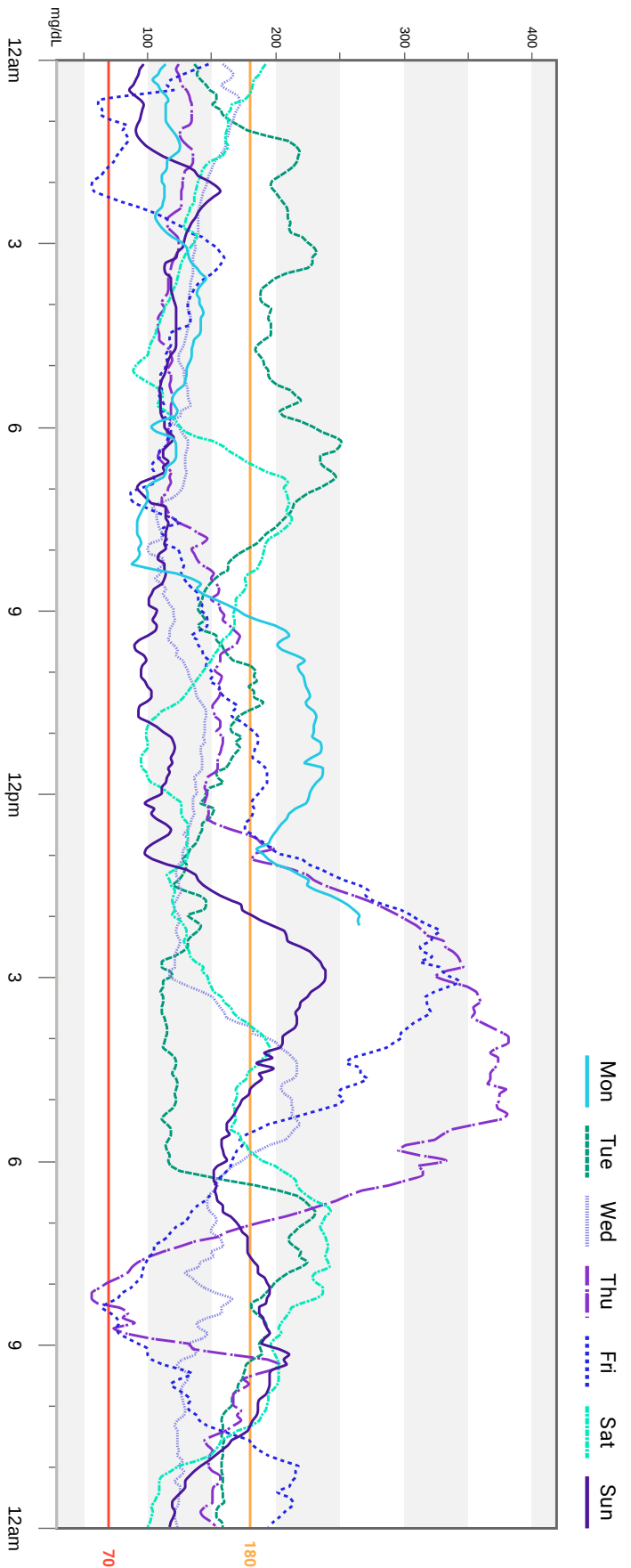
Patient a02 G6 Pro | ID: don't delete | DOB: Jan 1, 2001

Mon
Tue
Wed
Thu
Fri
Sat
Sun

Overlay

11 days | Fri Feb 14, 2020 - Mon Feb 24, 2020
Week 1 | Fri Feb 14, 2020 - Mon Feb 17, 2020

Patient a02 G6 Pro | ID: don't delete | DOB: Jan 1, 2001

Mon — Tue — Wed — Thu — Fri — Sat — Sun

Dexcom G6 Pro

Daily
11 days | Fri Feb 14, 2020 - Mon Feb 24, 2020

dexcom CLARITY

Patient's Daily View

Legend

CALIBRATIONS		CARBS		HEALTH		FAST-ACTING INSULIN / INSULIN		LONG-ACTING INSULIN	ALERTS
EXERCISE		MULTIPLE EVENTS							

Mon, Feb 24, 2020
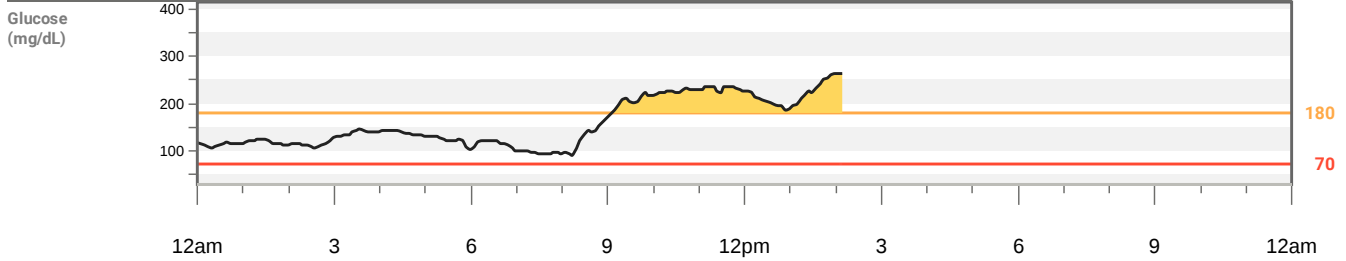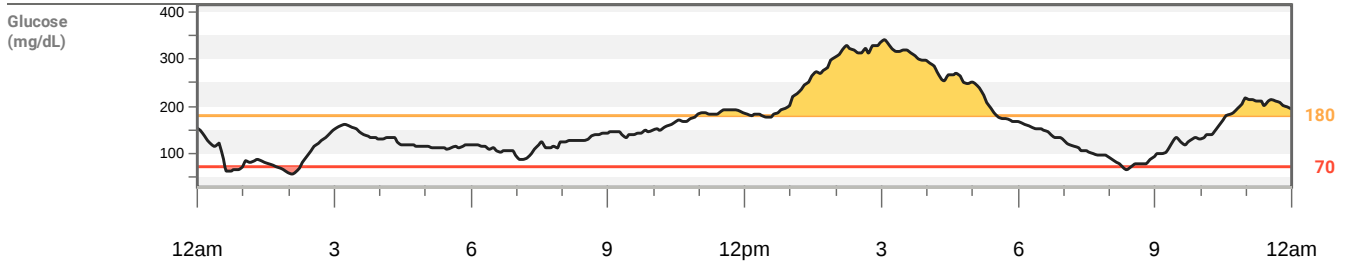
Glucose (mg/dL)

Sun, Feb 23, 2020

Glucose (mg/dL)

Sat, Feb 22, 2020

Glucose (mg/dL)

Fri, Feb 21, 2020

Glucose (mg/dL)

Daily

11 days | Fri Feb 14, 2020 - Mon Feb 24, 2020
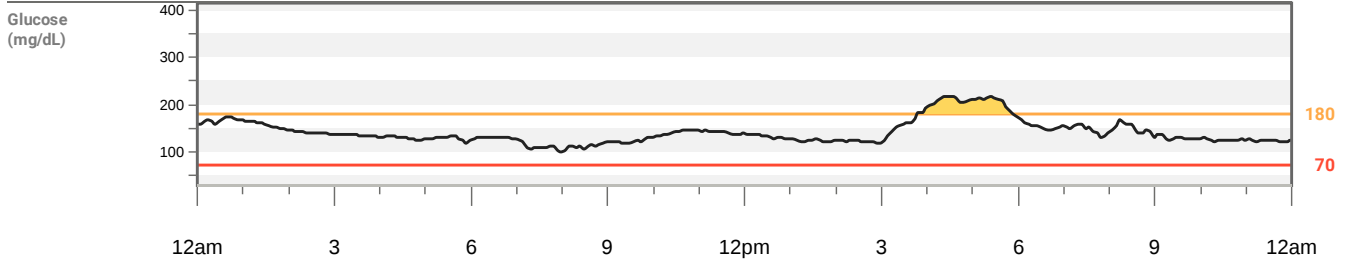
Patient's Daily View

Legend

◐ CALIBRATIONS

🍴 CARBS

♥ HEALTH

💉 FAST-ACTING INSULIN / INSULIN

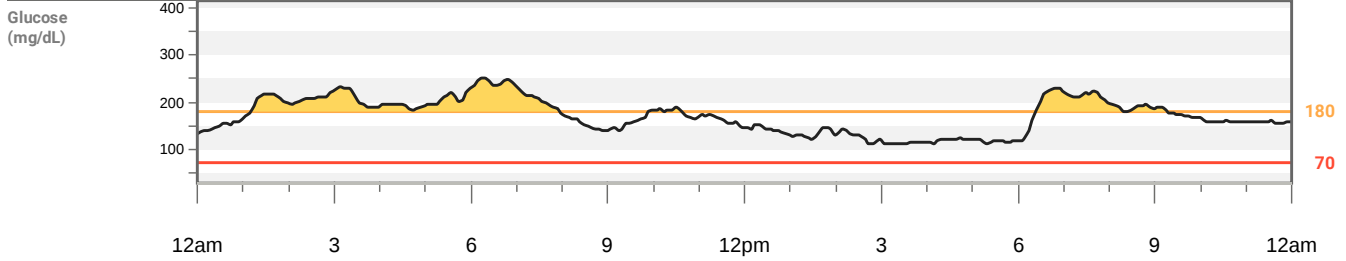🕐 LONG-ACTING INSULIN

📢 ALERTS

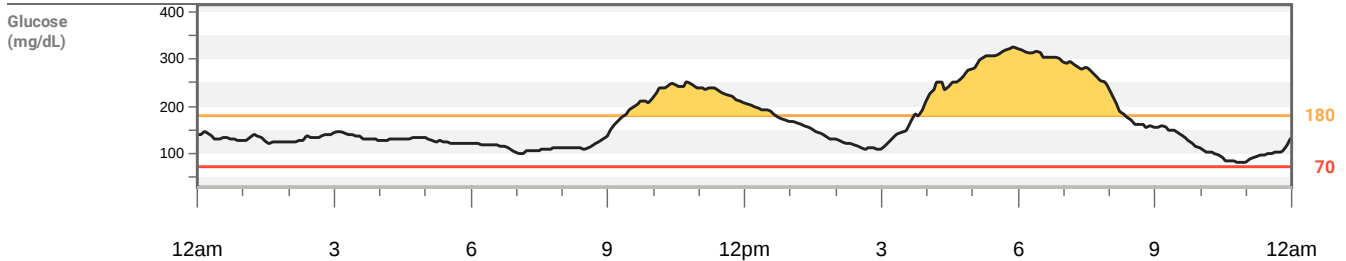🏃 EXERCISE

▢ MULTIPLE EVENTS

Thu, Feb 20, 2020
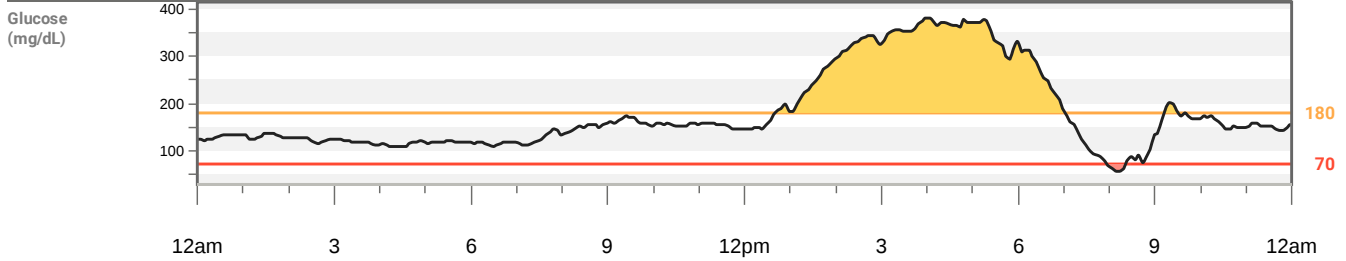
Glucose (mg/dL)

Wed, Feb 19, 2020

Glucose (mg/dL)

Tue, Feb 18, 2020

Glucose (mg/dL)

Mon, Feb 17, 2020

Glucose (mg/dL)

Data uploaded: Fri, Feb 28, 2020 3:25 PM PST   00386270000491 • Dexcom CLARITY v3.29.2 • PN 350-0011 • DOM 2020-06-30

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Daily

11 days | Fri Feb 14, 2020 - Mon Feb 24, 2020

dexcom CLARITY

Patient's Daily View

Legend

CALIBRATIONS	**CARBS**	**HEALTH**
FAST-ACTING INSULIN / INSULIN	**LONG-ACTING INSULIN**	**ALERTS**
EXERCISE	**MULTIPLE EVENTS**	

Sun, Feb 16, 2020
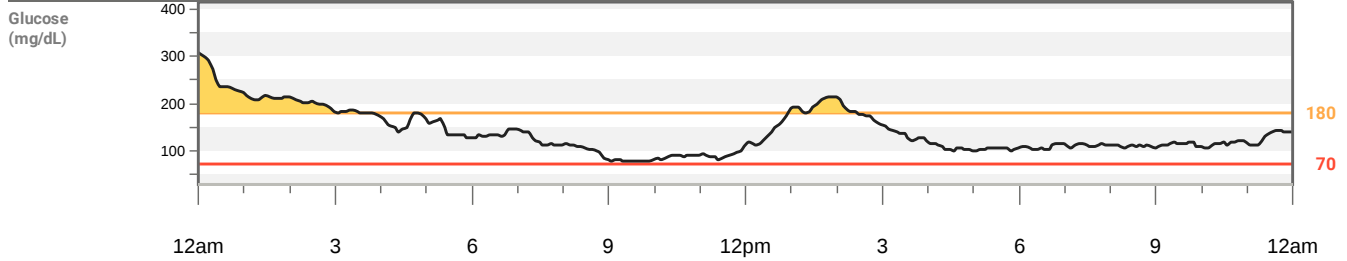
Sat, Feb 15, 2020

Fri, Feb 14, 2020

Generated at: Mon, Jul 6, 2020 4:10 PM PDT
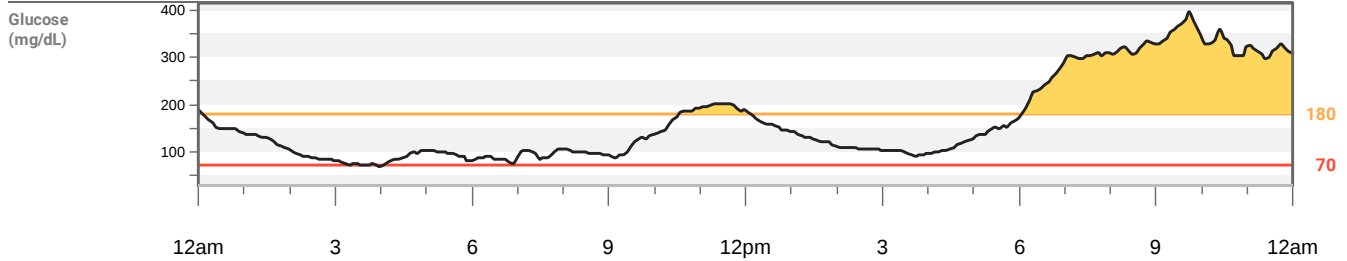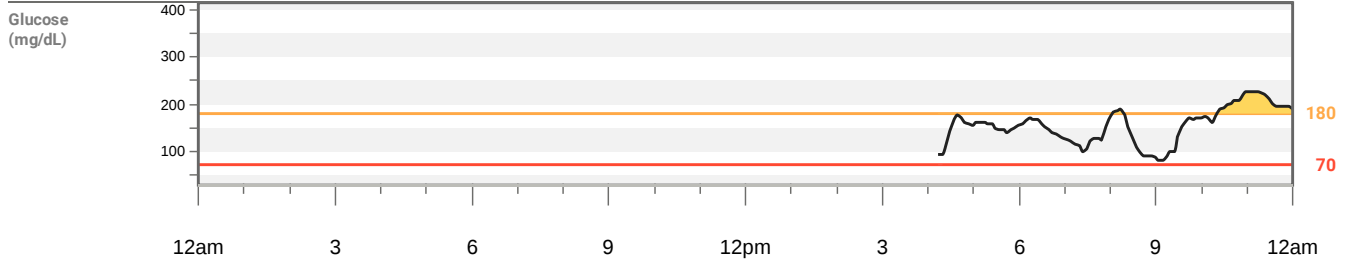
Daily Statistics

11 days | Fri Feb 14, 2020 - Mon Feb 24, 2020

Patient a02 G6 Pro | ID: don't delete | DOB: Jan 1, 2001

☀ 6:00 AM - 10:00 PM ■ Very low < 54 ■ Low 54 - 70 ■ In range 70 - 180 ■ High 180 - 250 ■ Very High > 250
☾ 10:00 PM - 6:00 AM ■ Very low < 54 ■ Low 54 - 70 ■ In range 70 - 180 ■ High 180 - 250 ■ Very High > 250

Daily Statistics	Mon	Tue	Wed	Thu	Fri	Sat	Sun
Time in Range							
% Very High	10	<1	0	21	11	11	1
% High	24	42	9	7	19	20	21
% In Range	66	57	91	70	67	68	78
% Low	0	0	0	2	3	<1	0
% Very Low	0	0	0	0	0	0	0
# Readings	458	288	288	288	382	576	576
Min	79	110	100	56	56	69	76
Max	326	251	218	382	343	397	304
Mean	164	171	141	181	160	162	140
Std. Dev.	61	37	25	87	64	71	43
Quartile 25	118	141	124	119	114	106	108
Median	136	167	133	151	148	142	122
Quartile 75	212	199	151	198	190	193	176
IQR	94	58	27	79	76	87	68
IQ Std. Dev.	28	17	7	17	21	25	20
SD Mean	3	2	1	5	3	3	2
%CV	38	22	18	48	40	44	31

Data uploaded: Fri, Feb 28, 2020 3:25 PM PST   00386270000491 • Dexcom CLARITY v3.29.2 • PN 350-0011 • DOM 2020-06-30   11 of 13

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Hourly Statistics

11 days | Fri Feb 14, 2020 - Mon Feb 24, 2020

Patient a02 G6 Pro | ID: don't delete | DOB: Jan 1, 2001

☀ 6:00 AM - 10:00 PM ■ Very low < 54 ■ Low 54 - 70 ■ In range 70 - 180 ■ High 180 - 250 ■ Very High > 250
☾ 10:00 PM - 6:00 AM ■ Very low < 54 ■ Low 54 - 70 ■ In range 70 - 180 ■ High 180 - 250 ■ Very High > 250

Hourly Statistics	12am-1am	1am-2am	2am-3am	3am-4am	4am-5am	5am-6am	6am-7am	7am-8am	8am-9am	9am-10am	10am-11am	11am-12pm
Time in Range												
% Very High	4	0	0	0	0	0	1	0	0	0	<1	0
% High	12	18	20	17	11	10	13	19	3	17	30	40
% In Range	81	79	77	82	89	90	86	81	97	83	69	60
% Low	3	3	3	1	0	0	0	0	0	0	0	0
% Very Low	0	0	0	0	0	0	0	0	0	0	0	0
# Readings	120	120	120	120	120	120	120	120	120	120	120	120
Min	61	57	56	69	71	80	73	82	80	76	81	81
Max	304	218	225	232	196	229	251	226	190	222	251	239
Mean	147	141	138	138	130	127	132	128	128	143	158	161
Std. Dev.	47	41	39	36	28	31	44	40	27	40	49	48
Quartile 25	115	119	115	119	113	110	110	101	107	110	120	117
Median	140	134	134	133	127	119	118	112	120	145	156	156
Quartile 75	167	162	145	150	138	130	132	138	149	168	186	200
IQR	52	43	29	31	25	20	22	37	42	58	66	83
IQ Std. Dev.	14	12	7	7	7	5	7	7	13	15	16	23
SD Mean	4	4	4	3	3	3	4	4	2	4	4	4
%CV	32	29	28	26	22	24	33	31	21	28	31	30

Hourly Statistics	12pm-1pm	1pm-2pm	2pm-3pm	3pm-4pm	4pm-5pm	5pm-6pm	6pm-7pm	7pm-8pm	8pm-9pm	9pm-10pm	10pm-11pm	11pm-12am
Time in Range												
% Very High	0	14	24	22	25	20	19	18	10	10	10	10
% High	29	27	15	20	28	15	28	26	36	26	17	20
% In Range	71	59	61	58	47	65	53	55	49	64	73	70
% Low	0	0	0	0	0	0	0	<1	5	0	0	0
% Very Low	0	0	0	0	0	0	0	0	0	0	0	0
# Readings	120	120	110	108	118	120	120	120	120	120	120	120
Min	98	104	103	89	91	99	101	69	56	79	79	86
Max	226	306	346	382	382	381	320	311	336	397	362	331
Mean	155	173	185	191	196	191	194	181	164	174	167	163
Std. Dev.	32	56	83	87	81	75	64	71	71	71	63	63
Quartile 25	131	125	120	122	121	145	150	115	106	126	123	119
Median	148	149	138	160	188	168	167	173	162	166	158	142
Quartile 75	183	217	239	227	251	214	237	239	195	195	182	198
IQR	52	92	119	105	131	69	87	124	89	69	59	78
IQ Std. Dev.	17	30	37	30	35	17	30	38	30	23	16	21
SD Mean	3	5	8	8	7	7	6	6	6	7	6	6
%CV	20	32	45	45	42	40	33	39	43	41	38	39

Generated at: Mon, Jul 6, 2020 4:10 PM PDT

AGP

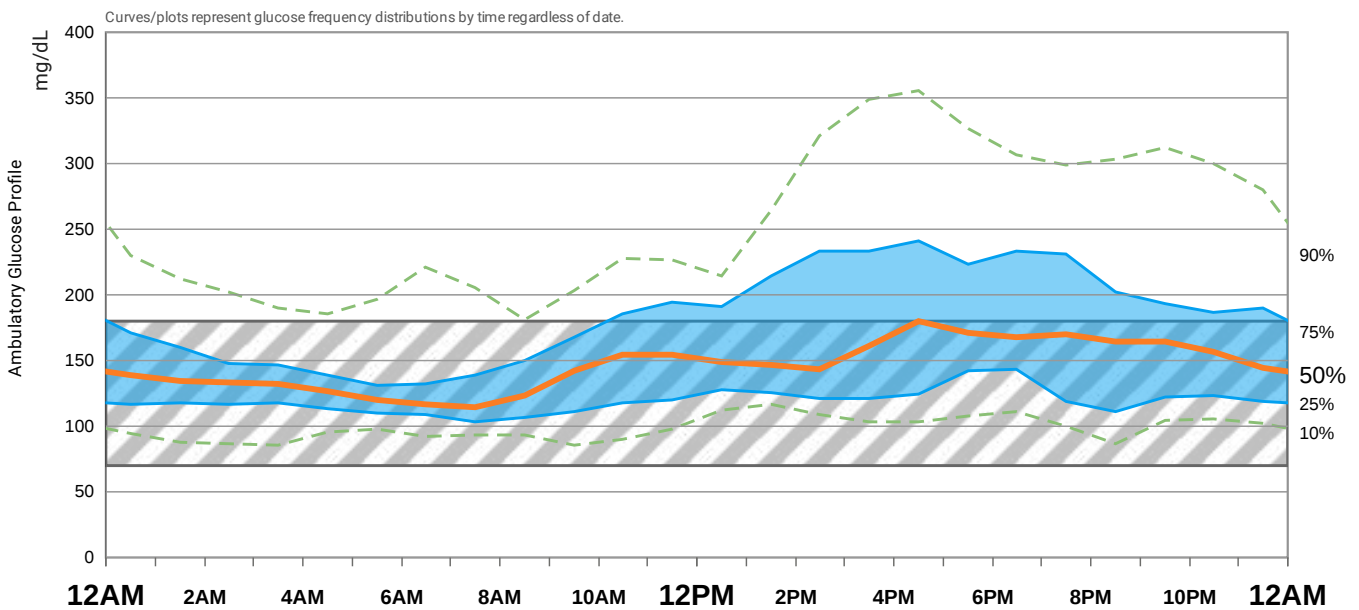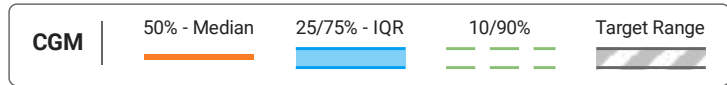**11 days** | Fri Feb 14, 2020 - Mon Feb 24, 2020

Patient a02 G6 Pro | ID: don't delete | DOB: Jan 1, 2001

Dexcom | captūrAGP®

Patient a02 G6 Pro
Fri Feb 14, 2020 - Mon Feb 24, 2020   (9.9 days)

Glucose Statistics									
Avg Glucose mg/dL	**Very Low** < 54 mg/dL	**Low** < 70 mg/dL	**In Target Range** 70 - 180 mg/dL	**High** > 180 mg/dL	**Very High** > 250 mg/dL		**Coefficient of Variation**	**SD mg/dL**	**% Time CGM Active**
158	**0.0%**	**0.6%**	**71.0%**	**28.4%**	**7.7%**		**38.4%**	**61**	**100.0%**
Glucose Exposure			Glucose Ranges				Glucose Variability		Data Sufficiency

CGM	50% - Median	25/75% - IQR	10/90%	Target Range

Curves/plots represent glucose frequency distributions by time regardless of date.

The Y axis and target range are the same as on the Ambulatory Glucose Profile graph above.
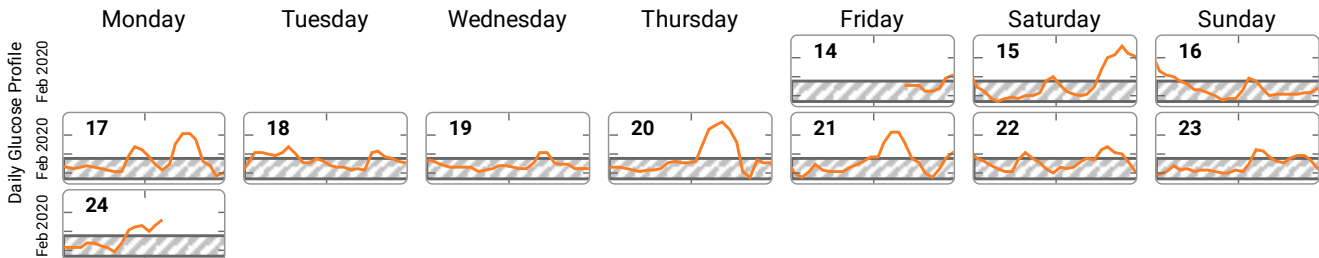
U.S. Patent No. Des. 773,478, patents pending – HealthPartners Institute dba International Diabetes Center – All Rights Reserved. CaptūrAGP v. 3.2

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Medtronic iPro2

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Pattern Snapshot for Sample M. Patient
Sep 28 - Oct 5, 2009

(8 days) Medtronic iPro2 Recorder #123456

Avg SG: **119 mg/dL**

Estimated A1C [1]:

  5.8% (40 mmol/mol) calculated from SG values

Time in range: **22% Above 150 mg/dL**

71% in target range

7% Below 70 mg/dL

OBSERVED PATTERNS & SOME POSSIBLE CAUSES [2]

1 — Variable SG with Low SG
Overnight 23:00 - 6:00

3 day(s)	**50 - 80** mg/dL
2 day(s)	**< 50** mg/dL
3 day(s)	**> 150** mg/dL

- Oral medication(s) too high or incorrectly timed?
- Basal insulin injection in evening(s) too high or missed?
- Pre-meal insulin in prior evening(s) incorrectly timed or incorrect dose?
- Inconsistent food intake day before?
- Inconsistent exercise schedule day before?
- Alcohol consumed in prior evening(s)?

2 — Low SG
Pre-dinner 17:00 - 20:00

2 out of 8 days excursions observed:

2 day(s)	**50 - 70** mg/dL
0 day(s)	**< 50** mg/dL

- Oral medication(s) too high or incorrectly timed?
- Basal insulin injections too high?
- Dinner delayed?
- Exercised before dinner?

3 — High SG
Post-dinner 17:00 - 20:00

2 out of 8 days excursions observed:

0 day(s)	**180 - 250** mg/dL
2 day(s)	**> 250** mg/dL

- Oral medication(s) missed, too low, or incorrectly timed?
- Pre-dinner insulin incorrectly timed, too low, or missed?
- Insulin to carbohydrate ratio not optimal for pre-dinner insulin?
- High calorie or high carbohydrate foods?

| mg/dL | Avg 93 mg/dL | 96 mg/dL | 134 mg/dL | 131 mg/dL | 145 mg/dL | 100 mg/dL | 136 mg/dL | 113 mg/dL |

Mon Sep 28 Tue Sep 29 Wed Sep 30 Thu Oct 1 Fri Oct 2 Sat Oct 3 Sun Oct 4 Mon Oct 5 AVG

Target Meal Marker
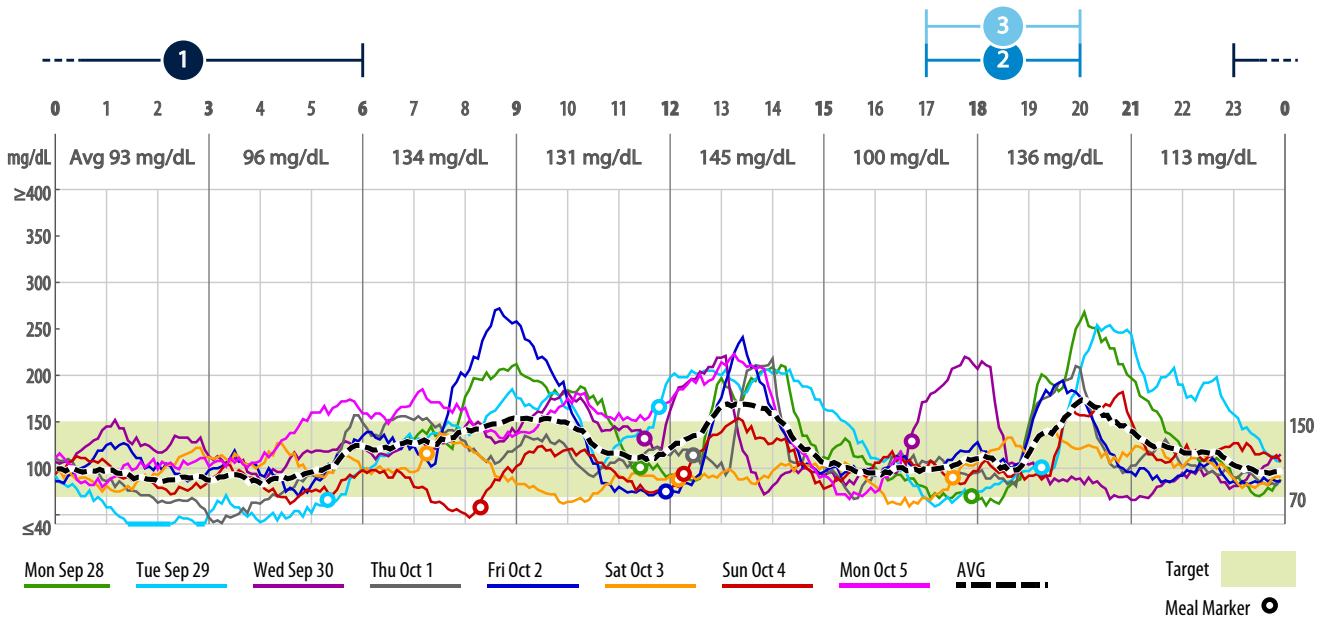
(1) Estimated A1C does not replace Lab measurement and is calculated from limited SG data.

(2) Suggested considerations are limited and do not replace the opinion or advice of the healthcare provider. Please see User Guide on how patterns and possible causes are identified.

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Daily Overlay for Sample M. Patient
Sep 28 - Oct 5, 2009 (8 days)

Medtronic iPro2 Recorder   #123456

Sensor Data (mg/dL)   A thicker flat sensor trace at 40 or 400 mg/dL indicates CGM values can be outside these limits.

Mon Sep 28 Tue Sep 29 Wed Sep 30 Thu Oct 1 Fri Oct 2 Sat Oct 3 Sun Oct 4 Mon Oct 5 Average
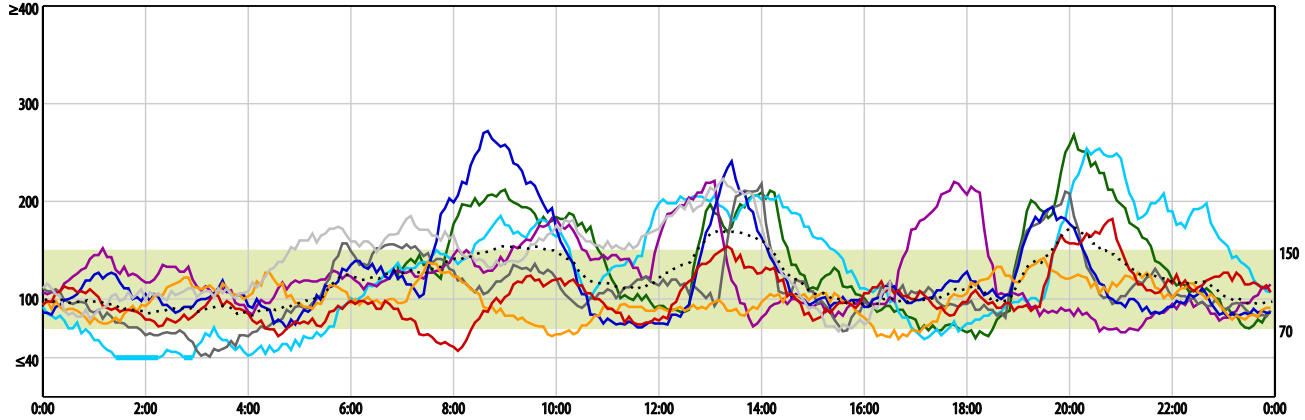
	Mon Sep 28	Tue Sep 29	Wed Sep 30	Thu Oct 1	Fri Oct 2	Sat Oct 3	Sun Oct 4	Mon Oct 5	Average / Total
# Sensor Values	205	288	288	288	288	288	288	199	2,132
Highest	268	254	221	218	272	142	182	223	272
Lowest	60	40	66	41	70	59	47	67	40
Average	141	128	123	111	124	99	102	139	119
Standard Dev.	52	58	36	35	46	18	25	38	43
MAD %	6.0	13.7	16.3	9.1	7.3	11.3	24.2	15.0	13.1
Correlation	0.99	0.84	N/A	N/A	N/A	N/A	0.94	0.93	0.91
# Valid Calibrations	4	4	5	3	4	5	4	5	34
Designation									

X: Use Clinical Judgment   S: No Sensor Data   C: No Calibration BGs

Excursion Summary (mg/dL/day)

	Mon Sep 28	Tue Sep 29	Wed Sep 30	Thu Oct 1	Fri Oct 2	Sat Oct 3	Sun Oct 4	Mon Oct 5	Average / Total
# Excursions	4	5	6	6	3	2	4	3	33
# High Excursions	3	3	5	4	3	0	2	2	22
# Low Excursions	1	2	1	2	0	2	2	1	11
AUC Above Limit	19.3	15.4	6.6	3.6	11.2	0.0	0.8	11.0	8.0
AUC Below Limit	0.2	4.0	0.1	1.2	0.0	0.4	0.6	0.0	0.9

Duration Distribution (hh:mm)
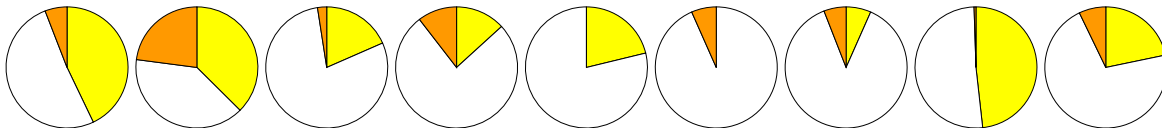
	Mon Sep 28		Tue Sep 29		Wed Sep 30		Thu Oct 1		Fri Oct 2		Sat Oct 3		Sun Oct 4		Mon Oct 5		Average/Total	
Above 150	7:20	43%	9:00	38%	4:25	18%	3:10	13%	5:05	21%	0:00	0%	1:35	7%	8:00	48%	38:35	22%
Within (70 - 150)	8:45	51%	9:30	39%	19:00	80%	18:20	77%	18:55	79%	22:25	93%	21:00	87%	8:30	51%	126:25	71%
Below 70	1:00	6%	5:30	23%	0:35	2%	2:30	10%	0:00	0%	1:35	7%	1:25	6%	0:05	1%	12:40	7%

![Medtronic]

Overlay by Meal for Sample M. Patient
Sep 28 - Oct 5, 2009
(8 days)

Medtronic iPro2 Recorder   #123456

Overlay by Meal Event (mg/dL)

Breakfast   Lunch   Dinner

Legend: Mon Sep 28, Tue Sep 29, Wed Sep 30, Thu Oct 1, Fri Oct 2, Sat Oct 3, Sun Oct 4, Mon Oct 5, Average
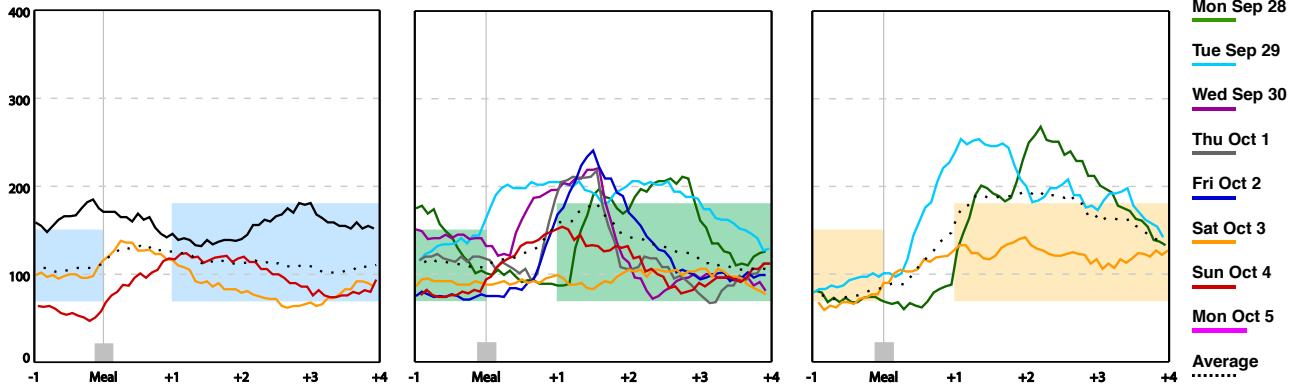
	Sleeping 3:00 - 6:00	Before Breakfast	After Breakfast	Before Lunch	After Lunch	Before Dinner	After Dinner	Evening 23:00 - 3:00	All Time Periods
Range	80 - 150	70 - 150	70 - 180	70 - 150	70 - 180	70 - 150	70 - 180	80 - 150	
Highest	174	185	181	178	241	101	268	158	268
Lowest	41	47	62	71	72	59	112	40	40
Average	96	107	114	112	148	78	185	94	112
Standard Dev.	29	46	31	30	49	11	50	24	44
# of Readings	252	36	72	84	168	36	72	336	1,056

Daily Average by Meal Event (mg/dL)

Below Target Range ▮   Above Target Range ▮

	Sleeping	Before Breakfast	After Breakfast	Before Lunch	After Lunch	Before Dinner	After Dinner	Evening	All Time Periods
Mon Sep 28				143	175	72	213	61	123
Tue Sep 29	59			136	197	90	217	127	134
Wed Sep 30	110			143	140			85	109
Thu Oct 1	81			118	141			100	104
Fri Oct 2	98			75	167			92	107
Sat Oct 3	108	99	83	91	97	70	126	90	97
Sun Oct 4	83	56	110	79	116			104	96
Mon Oct 5	134	166	151						145
Sep 28 - Oct 5	96	107	114	112	148	78	185	94	112

Duration Distribution (hh:mm)

	Sleeping	Before Breakfast	After Breakfast	Before Lunch	After Lunch	Before Dinner	After Dinner	Evening
Above	1:20 6%	0:55 31%	0:05 1%	0:35 8%	5:20 38%	0:00 0%	3:35 60%	0:15 1%
In Range	13:20 64%	1:05 36%	5:30 92%	6:25 92%	8:40 62%	2:05 69%	2:25 40%	21:40 77%
Below	6:20 30%	1:00 33%	0:25 7%	0:00 0%	0:00 0%	0:55 31%	0:00 0%	6:05 22%
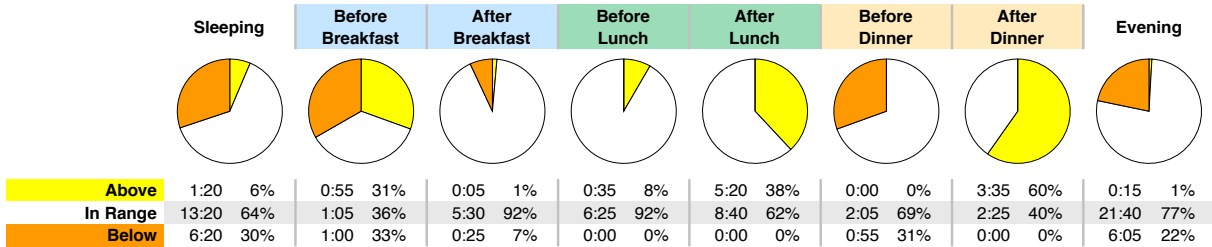
Night Time Sensor Data (mg/dL)

| Mon Sep 28 | Tue Sep 29 | Wed Sep 30 | Thu Oct 1 | Fri Oct 2 | Sat Oct 3 | Sun Oct 4 | Mon Oct 5 | Average |
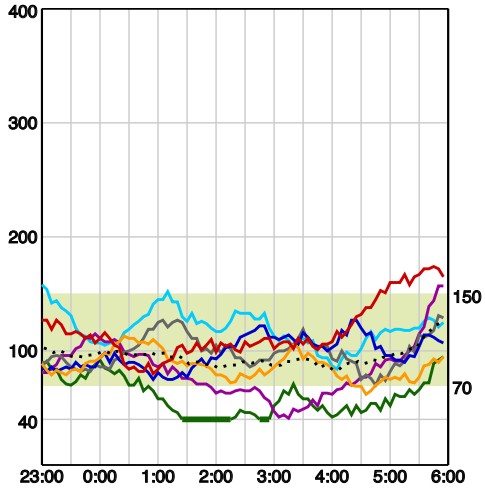
Notes:

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Daily Summary for Sample M. Patient
Sep 28 - Oct 5, 2009 (8 days)

Medtronic iPro2 Recorder   #123456

🖊 Meds 🗴 Insulin   **Meal:** 🤚 Unknown size 🤚 Small 🤚 Medium 🤚 Large   ✍ Note ▨ Target Range

🔴 BG ◎ Calibration BG   **Exercise:** 🏃 Unknown intensity 🏃 Light 🏃 Moderate 🏃 Intense   🌙☀ Bedtime / Wake-up

A thicker flat sensor trace at 40 or 400 mg/dL indicates CGM values can be outside these limits.

Mon Sep 28 (mg/dL)   Sensor ———

Tue Sep 29 (mg/dL)   Sensor ———
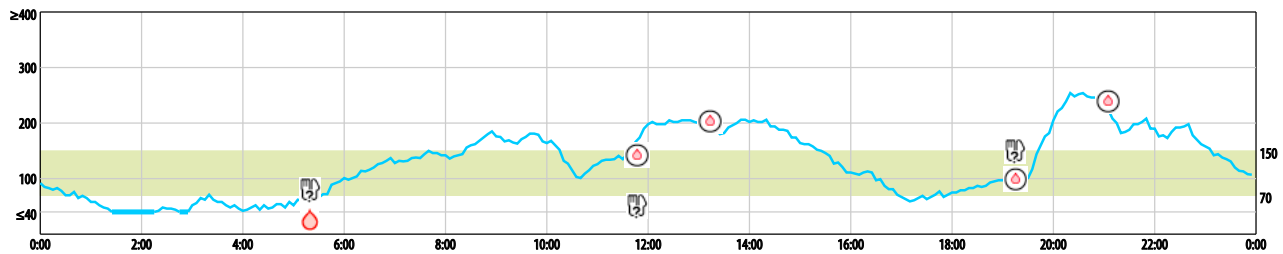
Wed Sep 30 (mg/dL)   Sensor ———
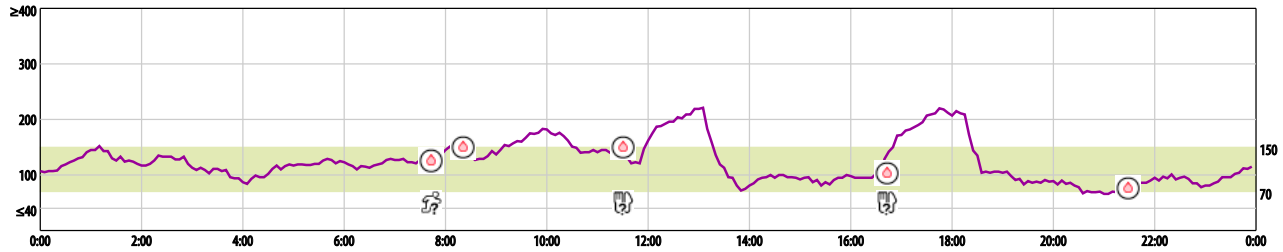
Thu Oct 1 (mg/dL)   Sensor ———
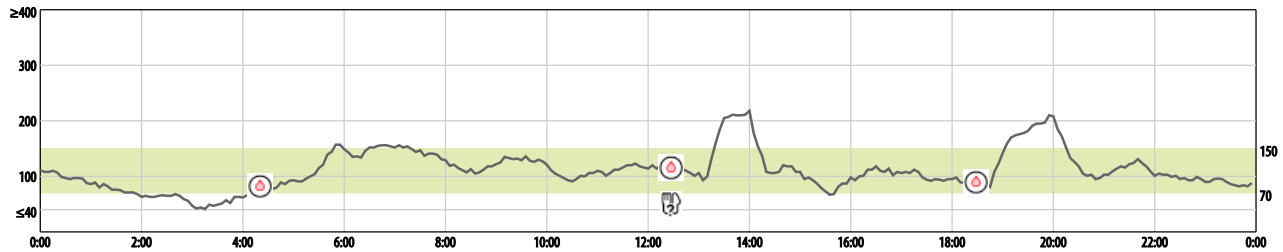
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Page: 1 Printed: 12/4/18, 9:53

5 of 8

🖊 Meds   📦 Insulin   **Meal:**   ⬓ Unknown size   🍴 Small   🍴🍴 Medium   🍴🍴 Large   🔖 Note   ▨ Target Range

🔴 BG   ◉ Calibration BG   **Exercise:**   🏃 Unknown intensity   🏃 Light   🏃 Moderate   🏃 Intense   🌙☀ Bedtime / Wake-up

A thicker flat sensor trace at 40 or 400 mg/dL indicates CGM values can be outside these limits.

Fri Oct 2 (mg/dL)   Sensor ——
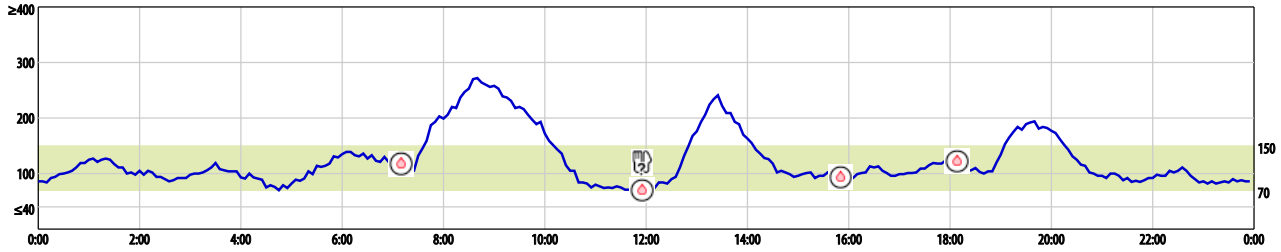
Sat Oct 3 (mg/dL)   Sensor ——
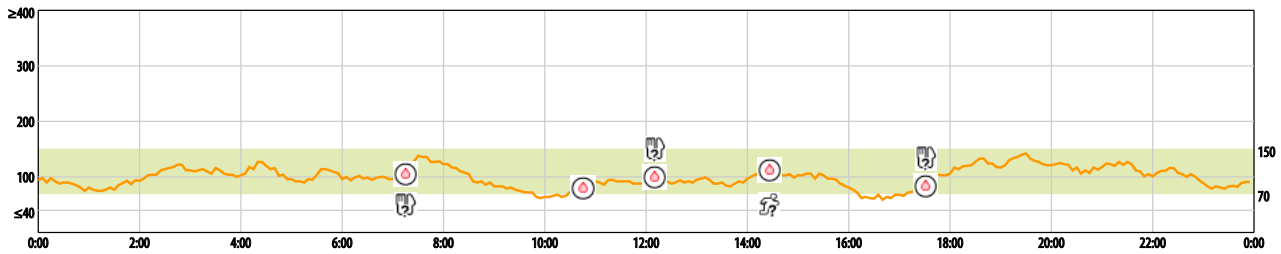
Sun Oct 4 (mg/dL)   Sensor ——
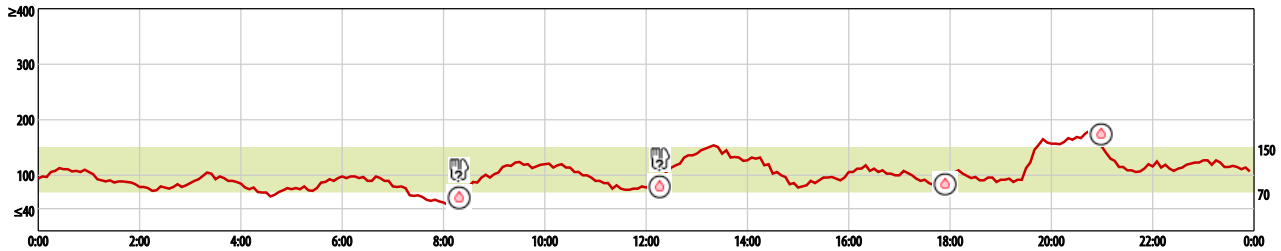
Mon Oct 5 (mg/dL)   Sensor ——
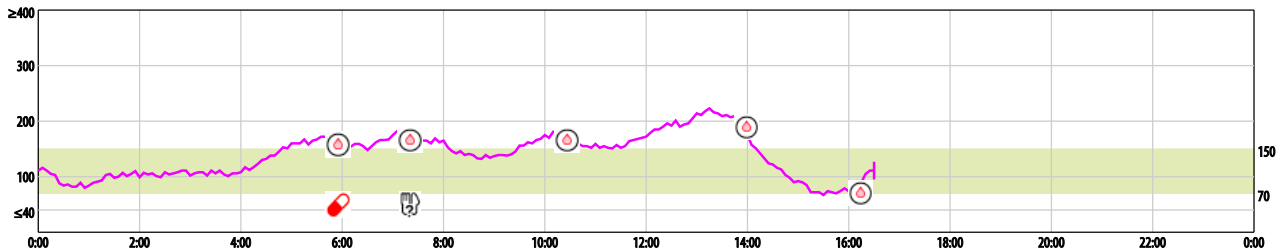
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Patient Notes for Sample M. Patient
Sep 28 - Oct 5, 2009

(8 days)　　　　　　　　Medtronic iPro2 Recorder　　　　　　　#123456

Date and Time	Event		Event Details
Monday September 28, 2009			
0:00:00	📝	Note	Toujeo....
7:02:00	⊙	BG	130 mg/dL
11:25:00	✋	Meal	Unknown size
	⊙	BG	100 mg/dL
17:53:00	✋	Meal	Unknown size
	⊙	BG	72 mg/dL
18:31:00	🔴	BG	30 mg/dL
	💊	Medication	
20:49:00	⊙	BG	214 mg/dL
Tuesday September 29, 2009			
5:19:00	✋	Meal	Unknown size
	🔴	BG	30 mg/dL
11:47:00	✋	Meal	Unknown size
	⊙	BG	142 mg/dL
13:13:00	⊙	BG	204 mg/dL
19:15:00	✋	Meal	Unknown size
	⊙	BG	100 mg/dL
21:05:00	⊙	BG	240 mg/dL
Wednesday September 30, 2009			
7:43:00	🏃	Exercise	Unknown intensity
	⊙	BG	126 mg/dL
8:21:00	⊙	BG	150 mg/dL
11:30:00	✋	Meal	Unknown size
	⊙	BG	150 mg/dL
16:43:00	✋	Meal	Unknown size
	⊙	BG	104 mg/dL
21:28:00	⊙	BG	76 mg/dL
Thursday October 1, 2009			
4:20:00	⊙	BG	82 mg/dL
12:27:00	✋	Meal	Unknown size
	⊙	BG	116 mg/dL
18:28:00	⊙	BG	90 mg/dL
Friday October 2, 2009			
7:10:00	⊙	BG	118 mg/dL
11:55:00	✋	Meal	Unknown size
	⊙	BG	70 mg/dL
15:50:00	⊙	BG	94 mg/dL
18:08:00	⊙	BG	122 mg/dL

-Monday October 5, 2009

Date and Time	Event	Event Details		
Saturday October 3, 2009				
7:15:00		Meal	Unknown size	
		BG	106 mg/dL	
10:45:00		BG	80 mg/dL	
12:10:00		Meal	Unknown size	
		BG	100 mg/dL	
14:26:00		Exercise	Unknown intensity	
		BG	112 mg/dL	
17:31:00		Meal	Unknown size	
		BG	84 mg/dL	
Sunday October 4, 2009				
8:18:00		Meal	Unknown size	
		BG	60 mg/dL	
12:16:00		Meal	Unknown size	
		BG	80 mg/dL	
17:54:00		BG	84 mg/dL	
20:59:00		BG	174 mg/dL	
Monday October 5, 2009				
5:55:00		BG	158 mg/dL	
		Medication		
7:20:00		Meal	Unknown size	
		BG	166 mg/dL	
10:26:00		BG	166 mg/dL	
13:59:00		BG	190 mg/dL	
16:14:00		BG	70 mg/dL	

RESOURCES:
MANUFACTURER SUPPLIED
ONLINE TRAINING/TUTORIALS

- **Abbott Tutorials**   **CLICK HERE**

- **Dexcom Tutorials**   **CLICK HERE**

- **Medtronic Tutorials**   **CLICK HERE**

RESOURCES:
Danatech product specifications for all diabetes technology devices and products and online learning

ADCES
Association of
**Diabetes Care & Education
Specialists**

danatech
POWERED BY **ADCES**

ADCES Danatech - **www.Danatech.org**

Danatech includes access to CGM device information, including technical specifications and resources for healthcare professionals and people with diabtees. Free subscription access is avaiable to ADCES, National Associaion of School Nurses (NASN) and American Society of Endocrine Physician Assistants (ASEPA) members.

A 14.5 hour CE-accredited CGM in Practice Certificate Program with digital badge is available free to ADCES, NASN, and ASEPA members. Requires username and password.

Courses that are part of the CGM in Practice Certificate Program Include:
- Continuous Glucose Monitoring: Connecting the Dots (5 CE)
- Continuous Glucose Monitoring: Real World Case Studies in Pattern Management (4.5 CE)
- Webinar: CGM Data in Clinical Practice (1.5 CE)
- Webinar: The Ins and Outs of Starting a Continuous Glucose Monitoring Program (1.5 CE)
- Case Study Videos - Discussing CGM in Diabetes: The Diabetes Care and Education Specialist's Role (1.0 CE)
- CGM Certificate Post-Learning Assessment (1.0 CE)

Courses may also be taken individually for CE credit.

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wish to thank the following contributors and reviewers:

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