Can J Diabetes 47 (2023) 389–397

Contents lists available at ScienceDirect

Canadian Journal of Diabetes

journal homepage: www.canadianjournalofdiabetes.com

Special Article

Do-It-Yourself Automated Insulin Delivery: A Health-care Practitioner User's Guide

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Introduction

The key message of the Diabetes Canada position statement on do-it-yourself automated insulin delivery (DIY AID) is that clinicians should support people living with type 1 diabetes (T1D) and their caregivers in whichever method of insulin delivery they choose (for the purpose of this guide, PWD will refer to people with T1D and their caregivers). This health-care practitioner (HCP) user's guide is being published alongside the position statement to provide clinicians with guidance on how to be inclusive of DIY AID, from discussing therapeutic options to supporting PWD during follow-up care, helping them improve their glycemic metrics and quality of life, and to lessen burden.

The nature of open-source insulin delivery systems is that the developers rapidly iterate adding new "branches" of code that allow for improvements in the system much faster than commercial AID systems, which require regulatory approval prior to making changes to algorithms and features. This may mean that, as soon as this user's guide is published, there could be new nuances to the system that will make it out of date. In reality, with the rapidly evolving evidence base in diabetes care today, this is true of all guidelines. The aim of this paper is to provide clinicians with an understanding of the evidence-based DIY AID systems reviewed in the corresponding position statement, which includes the following open-source systems: Loop, AndroidAPS, and OpenAPS. We recognize that additional open-source systems are available, such as iAPS (previously known as free APSX or FAX). While these systems have some similarities, there are additional settings and parameters that are beyond the scope of this paper. Additional adjustable parameters in newer branches of DIY algorithms may include terminology that does not build on existing continuous subcutaneous insulin infusion (CSII) language, making it difficult for HCPs to support individuals in optimizing settings; an effort by developers to consult with the diabetes education community would advance translation of DIY AID into clinical practice.

Discussing DIY AID as a Therapeutic Option

Clinicians may feel uncertain about *if* or *how* they should respond to or initiate discussions about DIY AID in practice. As highlighted in the position statement, HCPs should discuss all available treatment options that have evidence of benefit for PWD, together with risks and benefits. This encompasses varying levels of technology and AID, including both commercial and DIY options (Figure 1). We must challenge our own assumptions and biases which may influence the individuals with whom we discuss advanced technologies. Evidence has shown that some PWD whom HCPs may have assumed were not appropriate candidates for commercial AID were able to be successful and, in some cases, did better than those who were labelled as educated and technologically competent [1]. During treatment option discussions, it is imperative to use shared decision-making, while respecting autonomy, as PWD make choices about their best personal options. These options should be revisited on an ongoing basis given the dynamic nature of readiness for change, access to coverage, and alternative options available.

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https://doi.org/10.1016/j.jcjd.2023.06.001

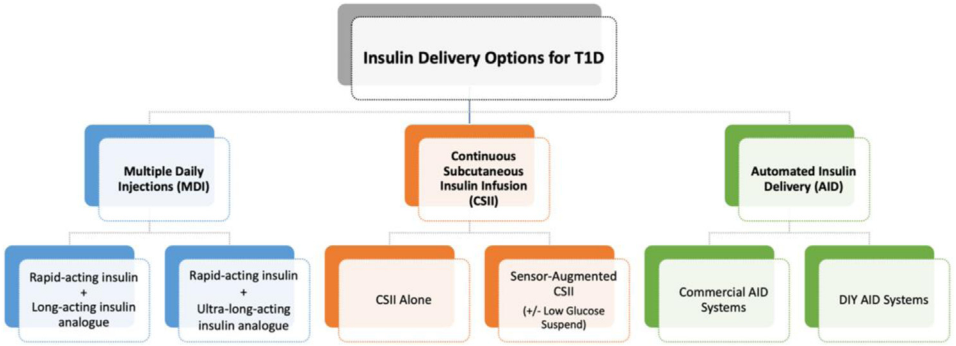


Figure 1. Including DIY AID as one of the insulin delivery options to discuss with people with T1D and their caregivers. *DIY*, do-it-yourself; *T1D*, type 1 diabetes.

Preparing PWD for a Successful Transition to DIY AID

While we encourage PWD to work through the steps of building their own DIY AID systems, we should provide guidance to help prepare them for a successful transition. Direct PWD to reliable resources for information, instructions, and support (Textbox 1). Encourage PWD to research the various systems, considering that the requirements for each system vary and are ever evolving. This may include compatible insulin pumps/pods, smartphones, linking devices, and computer requirements to build the code.

Clinically, preparation education should be comparable to CSII and commercial AID systems, including essential diabetes self-management education (e.g. troubleshooting hypo- and hyperglycemia, diabetic ketoacidosis prevention and treatment, etc.), the basic concepts of pump therapy and continuous glucose monitoring (CGM), and key concepts of AID (Figure 2) [2]. A strong foundation can contribute to a successful and safe transition to DIY AID use.

Across all platforms, PWD are encouraged to start in "open-loop" first, where the system operates using the pump settings with no automation [3–5]. AndroidAPS users are forced to start in open-loop and are required to read and learn about all the features before the automation can be unlocked. HCPs can assist with evaluating pump settings before "closed-loop" functionality is initiated. While we encourage optimizing pump settings for safety and optimal performance, we emphasize that this does not translate to *perfecting* pump settings. The very nature of AID encompasses that automated delivery is able to compensate for inter- and intraday variability in insulin requirements, as well as accommodate for miscalculated (or sometimes even omitted) carbohydrate inputs. The focus should be on ensuring that the core pump settings are reflective of physiologic insulin requirements.

Finally, use shared decision-making to establish realistic and individualized goals. This should include not only numeric glycemic goals, but also personal goals about daily management and disease burden.

Textbox 1. DIY AID online resources

Community support:
Looped Facebook group (#WeAreNotWaiting): https://www.facebook.com/groups/theloopedgroup/
Discord (#WeAreNotWaiting): https://discord.gg/hvugdvc5ms

Multiple other online message groups and forums have been reported to be sources of support for users of the various DIY AID systems, including Telegram, Zulipchapt, and Gitter.

System-specific information, education, and build instructions:
LoopDocs: https://loopkit.github.io/loopdocs/
OpenAPS's documentation: https://openaps.readthedocs.io
Android APS's documentation: https://androidaps.readthedocs.io

Education:
Automated Insulin Delivery (e-book): www.artificialpancreasbook.com
Loop and Learn: www.loopnlearn.org

Navigating DIY AID to Optimize Settings

The high level of self-management taken on by PWD and/or their caregivers to use DIY AID systems is remarkable. While many will sacrifice considerable time and effort throughout initiation, HCPs should consider that the technological literacy skills for setup may differ from the health literacy skills required for evaluating settings and navigating diabetes management challenges [6]. While self-management in T1D is encouraged and support from the online community is very useful [7–9], HCP support remains invaluable.

The landscape of rapidly advancing diabetes technologies can be overwhelming. As with standard CSII and commercial AID systems, HCPs must have a basic understanding of the key system characteristics to effectively support PWD during follow-up care. This creates opportunities to collaborate on self-management plans and empower PWD as they strive to reach glycemic and personal goals, all while maintaining a trusting relationship with their HCPs.

Given the substantial differences across AID systems, the CARES paradigm was developed for HCPs to simplify understanding of the key characteristics for each system [10]. Applying the CARES framework to DIY AID systems allows us to address these clinically relevant questions (Figure 3).

***C**alculate:* *How does the system calculate insulin delivery? [10]*

Loop, AndroidAPS, and OpenAPS systems all use predictive algorithms, each with their own unique features [11]. The systems predict the future glucose by considering real-time CGM (rtCGM) data, current pump settings, active insulin, and recent carbohydrate inputs [3,4]. Insulin delivery is adjusted (up or down) to bring the predicted glucose into target range [3,4,6]. The programmed basal rates act as the baseline from which temporary basal adjustments and/or proportions of calculated boluses are made. Basal adjustments and automatic boluses are accounted for in active insulin/insulin on board (e.g. if basal rates are temporarily increased, the

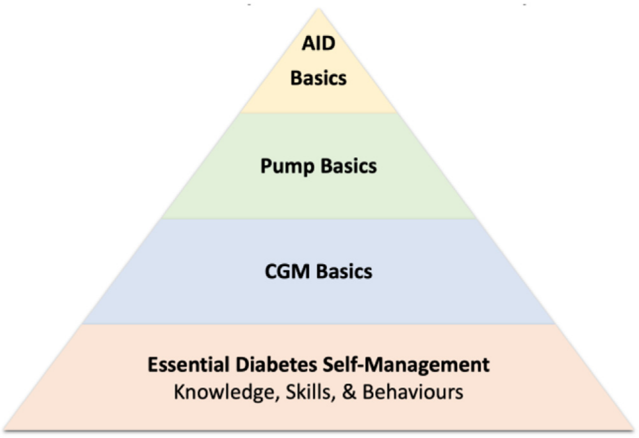


Figure 2. Essential education in preparation for do-it-yourself automated insulin delivery (AID) use. Prepared by Dr Revital Nimri and adapted from Phillip et al [2]. *AID*, automated insulin delivery; *CGM*, continuous glucose monitoring.

additional insulin is added to active insulin) [3]. Figure 4 shows how this information is displayed to the user.

Further details on the algorithms, including ongoing advancements to the systems, are openly available online (Textbox 1).

Adjust: *How can the user adjust delivery? Which parameters can be user-adjusted? [10]*

Understanding how to adjust insulin delivery is key for optimizing performance and safety. A key reason why many PWD choose DIY AID systems is the ability to customize more settings than with commercial systems [7,12]. DIY AID users have the ability to adjust nearly all standard pump settings (Textbox 2).

New users are encouraged to evaluate and adjust pump settings prior to enabling "closed-loop" functionality to avoid inappropriate insulin delivery [3,6]; this includes those switching from multiple daily injections (MDI), standard CSII, or other AID systems. Pump settings should meet individual and physiological insulin requirements [6]. See Table 1 for important considerations when evaluating the key settings. Basal rate evaluation should be prioritized, as inaccuracies may have a ripple effect, impairing the accuracy of other settings [3,6,13]. For example, inaccurately high basal rates may result in weaker carbohydrate ratios (CRs) and insulin sensitivity factors (ISFs). To prioritize safety, PWD should be encouraged to prioritize setting optimization for minimizing hypoglycemia risk before fine-tuning to achieve glycemic goals beyond the targets of the Diabetes Canada guidelines.

As with standard pump setting adjustments, users are encouraged to adjust 1 setting at a time to allow evaluation of the impact before proceeding further [4,5,10]. To evaluate settings, the combined CGM and insulin delivery data can be reviewed via Nightscout and/or Tidepool cloud-based systems (see Appendices A and B for report guides).

Some users choose to utilize the Autotune tool, which aids in calculating potential setting adjustments based on insulin delivery data. Careful consideration should be made to suggestions, and users are encouraged to review adjustments with their care teams. More information on Autotune is available at: https://openaps.readthedocs.io/en/latest/docs/customize-iterate/autotune.html.

Revert: *When does the system revert to traditional pump settings ("open-loop")? [10]*

If CGM data and/or communication with the pump is disrupted, the system reverts from "closed-loop" to "open-loop" [10]. Insulin delivery will continue using the standard pump settings.

Users can manually revert to "open-loop" at any time. They should consider this during illness and/or ketosis, when potential prolonged suspensions may create risk [10], and during periods of inaccurate CGM performance. Users should follow CSII guidance on managing ketosis in the event of an infusion set/pod failure, including monitoring glucose levels and ketones, and administering manual corrective insulin. If a manual injection is required via insulin pen/syringe, closed-loop functionality should remain turned off for the duration of the insulin action time since insulin-on-board calculations will not be accurate [2]. To be prepared for unexpected periods of "open-loop," we further emphasize the importance of assessing accuracy and safety of the standard pump settings and having a backup plan for subcutaneous injections should the pump or the infusion site fail.

Educate: *What are the essential education points for safety and optimization of use? [10]*

Users consistently report positive experiences with online support communities [6–9]; however, education from the healthcare team remains important. Education should be individualized, empowering, and collaborative, supporting PWD in their self-management practices. Ongoing education should be comparable to other AID systems, including the key points outlined in Table 2 (adapted from [10]).

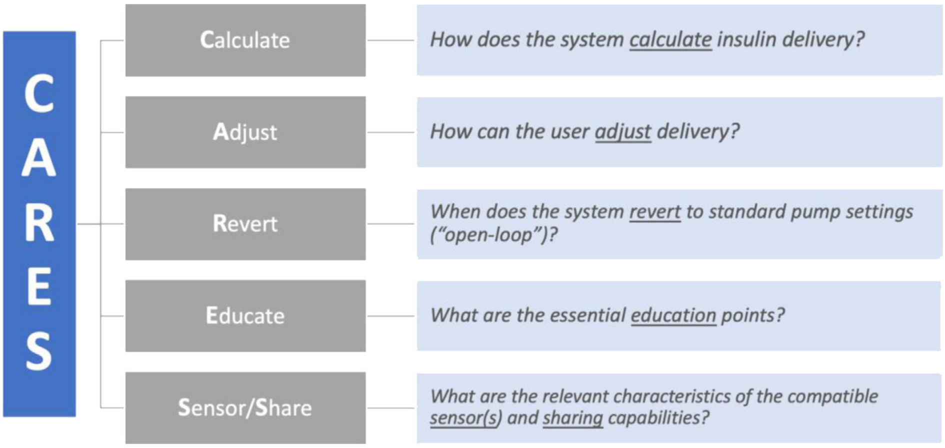
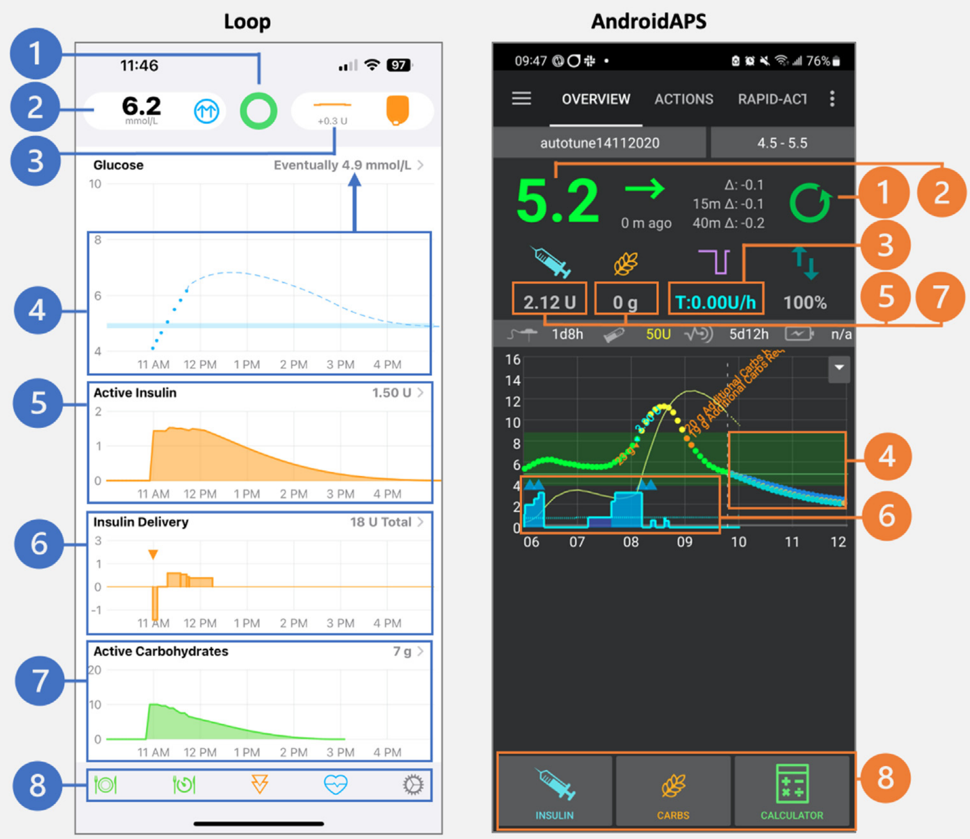


Figure 3. The CARES framework: Highlighting the key points of automated insulin delivery systems [10].



Key home screen items:

1) Loop status indicator: green loop indicates "closed-loop"functionality is active
2) Current CGM glucose value and trend arrow
3) Current temporary basal adjustment (from baseline programmed basal rate)
4) CGM tracing with algorithm-predicted future glucose
5) Current active insulin/insulin on board
6) Insulin delivery history (baseline represents programmed basal rates)
7) Current "carbs on board" (carbohydrates that have been entered, but not yet absorbed)
8) Tool bar, including bolus commands

Figure 4. Sample home screen displays from do-it-yourself automated insulin delivery systems demonstrating real-time calculations. *CGM*, continuous glucose monitoring.

Textbox 2. Adjustable pump settings with DIY AID systems (Loop, AndroidAPS, OpenAPS)*

- Basal rates
- Insulin sensitivity factors
- Carbohydrate ratios
- Correction range (including a preprandial option)
- Insulin model (i.e. duration of insulin action or active insulin time)
- Delivery limits
- Suspend thresholds

* *Additional parameters may require adjustments in newly developed DIY AID systems and may include terminology that does not build on existing continuous subcutaneous insulin infusion settings language.*

In addition to the key education points in Table 2, HCPs and PWD should collaborate on individualized strategies for mealtime dosing, exercise/physical activity, and circumstances with varying insulin requirements (shift work, hormonal changes, steroid use, travel, etc.).

Mealtime dosing: Preprandial bolus delivery is important to optimize postprandial glycemia, and should be adjusted further if postprandial hyperglycemia persists despite validating pump settings. Users can adjust the time of the carbohydrate entry to indicate a prebolus or a delayed bolus (which results in a bolus recommendation that considers insulin adjustments already made). To help minimize excursions, users may explore using the preprandial correction range (Loop), which prompts the system to increase delivery in an attempt to reach this tighter target until the meal bolus is delivered. Advanced meal assist (OpenAPS) allows the

Table 1
Clinical considerations for optimizing DIY AID settings

Step 1: Assess glycemia	Assess if glycemic goals have been met, including time in target range, time below range, time above range, and glycemic variability (coefficient of variation).
Step 2: Assess total daily dose	Optimal TDD is an important factor for calculating and assessing physiological basal and bolus insulin pump settings [13]. If not meeting glycemic targets, consider an adjusted TDD for use with TDD-based insulin dose calculations (e.g. if time in hypoglycemic range is >4%, reduce TDD by 10%–20%; use the reduced TDD in basal and bolus setting calculations). When using a DIY AID system, the actual TDD may be more reflective of the optimal TDD, since the system adjusts insulin delivery regularly to minimize hypo- and hyperglycemia [13].
Step 3: Evaluate basal rates	Prioritize basal rate evaluation, as inaccuracies may impair the accuracy of bolus settings [3,6,13]. • For adults with T1D, basal insulin represents 30% to 60% of the TDD [13,14]. • Multiple factors will influence the optimal basal percentage for an individual (e.g. someone on a low-carbohydrate diet will likely have a higher % basal; someone who is very active may have a lower % basal) [13]. • Young children have lower basal requirements, which change with age and across pubertal stages [15]. Actual basal delivery may be much higher than the total of programmed basal rates if the algorithm uses basal adjustments for corrections and/or covering unannounced carbohydrate intake. Consider this when assessing % basal. ***Practice tip:*** *When assessing and adjusting basal rates, compare the actual basal delivery with the programmed basal rates. Look for what happens in the absence of food and activity:* ➔ Consistently *increasing* basal (resulting in positive IOB): basal rates may be too low. Confirm if this is related to missed carbohydrate boluses. ➔ Consistently *decreasing* basal (resulting in negative IOB), especially if glucose drops below range: basal rates may be too high [3].
Step 4: Evaluate bolus settings	**Insulin sensitivity factor (ISF):** The ISF is used for correction bolus calculations *and* algorithm calculations for basal adjustments. ➔ If ISF is too strong: correction boluses *and* basal adjustments will be more aggressive when the glucose is predicted to be above target, and may result in hypoglycemia. ➔ If ISF is too weak, correction boluses *and* basal adjustments will be insufficient to achieve glucose targets. ***Practice tip:*** *Watch for fluctuating glucose levels among new DIY AID users, which are commonly linked with an inaccurate ISF* [3]. *For example, an ISF that is too strong will lead the system to overcompensate for both predicted high and low glucose levels, leading to a "roller coaster"—like glucose curve in the absence of food.* **Carbohydrate ratios (CRs):** The CRs should minimize postprandial glycemic excursions while minimizing the risk of hypoglycemia before the next meal [13]. To further optimize postprandial excursions, some users may more aggressively strengthen the CR, especially if basal reductions and/or suspensions are sufficient to minimize late postprandial hypoglycemia [6].
Additional setting considerations:	
Insulin model	The recommended models for all current rapid-acting insulins (including faster-acting aspart) default to 6-hour insulin action times [3], which reflects the pharmacodynamic profiles. Encourage using the 6-hour models to minimize insulin stacking [3,6]. ***Practice tip:*** *If switching from other systems, consider how using different models may impact other settings (i.e. switching from a 3-hour to a 6-hour duration time may require strengthening the ISF).*
Correction range	The correction range (or single value) is the glucose level that the system corrects to. Encourage new users, or those experiencing excessive hypoglycemia, to use a conservative range until basal rates and ISF have been evaluated. ***Preprandial override target:*** This additional user-set target can be temporarily activated before meals to increase insulin delivery before eating, and can help with postprandial glucose rises [3].
Safety settings	With DIY AID, users can customize settings beyond the abilities of commercial systems, where many delivery limits are set by the manufacturers. Therefore, extra attention should be drawn to these settings for safety: **Maximum basal rate:** • If insulin settings (above) are incorrect, the max basal will limit how much basal insulin the system can deliver as programmed or temporary basal adjustments. • This should be higher than the programmed basal rates to allow for effective temporary basal adjustments. Experienced users do not set this to exceed more than 3–4 times their average hourly basal rate [3]. • Consider that temp basal rates are set for 5-minute intervals. **Maximum bolus:** • This limits the maximum bolus that can be delivered in a single dose. • For safety, do not set this larger than a typical large meal bolus. **Suspend threshold:** • If the current or predicted glucose is below this threshold, basal delivery will suspend, and the system will not recommend a bolus [3]. • Balance risk of hypoglycemia with risk of potential prolonged suspensions. **CGM alerts:** Low and high CGM glucose alerts, with repeat/snooze times, should be used as safety nets, prompting PWD to take action if/when the system is not able to prevent episodes of hypo- and/or hyperglycemia.

CGM, continuous glucose monitoring; *DIY AID*, do-it-yourself automated insulin delivery; *IOB*, insulin on board; *ISF*, insulin sensitivity factor; *PWD*, person with diabetes; *T1D*, type 1 diabetes; *TDD*, total daily dose.

Table 2
Key self-management education points for DIY AID users (adapted from [10])

1. Establish and individualize goals and expectations	Collaborate to set realistic goals, while avoiding over-reliance on numeric targets [6]. Address personal goals around daily management and burden [6].
2. Adjust insulin pump settings to optimize performance	Review how to assess and self-adjust settings to reflect physiological requirements. Watch for inaccurate settings that may compensate for one another (e.g. a strong ISF that is compensating for an inaccurately weak CR and resulting in excess hypoglycemia).
3. Trust the system (minimize bolus overrides)	Over-interaction with the system may increase glycemic variability [1]. Discuss how insulin on board accumulates from temp basal increases and/or automatic boluses; overriding bolus recommendations may result in hypoglycemia.
4. Pre-bolus for meals	Initiate bolus delivery before eating (typically 10–20 minutes) to optimize postprandial glucose levels [2]. Adjust timing by considering meal composition, pre-meal glucose level, presence of gastroparesis, and individual patterns. Delayed boluses should be adjusted to minimize hypoglycemia risk since the system will increase insulin delivery as glucose levels rise [2,10]. If bolus is delayed by [2]: ➔ 30–60 minutes: consider decreasing by 50% ➔ >60 minutes: deliver system-recommended correction boluses only, as needed
5. Consider altering hypoglycemia treatment	Less carbohydrate may be required, depending on duration of suspension prior to a hypoglycemic event [6,10].
6. Use "Override Presets" or "Temporary Targets" to meet temporarily changing needs (e.g. increased/decreased activity levels, hormonal fluctuations, steroid use, travel)	This allows users to temporarily adjust the target range and/or insulin settings (basal rates, CRs, and ISFs) by a uniform percentage over a selected duration [3,6].
7. Review best practices for site management	Discuss site selection and rotation, skin preparation, and adhesion tips for both infusion sets/pods and sensors. PWD should be prepared to troubleshoot site failures and may require support managing skin irritation.
8. Review backup plan	Review considerations for reverting to open-loop or standard pump therapy (i.e. consider use of temp basal rates; may need to weaken CRs). Describe how to replace insulin by injection in the event of short-term and long-term interruption of therapy, or presence of ketones. This should include strategies using rapid-acting insulin alone and/or in combination with long-acting insulin. Review CSII guidance on prevention, monitoring, and managing ketosis, including the importance of having an accessible ketone meter or urine strips.
9. Know where to find reliable support and resources	Ensure PWD are familiar with the #WeAreNotWaiting online support group and open access documents for detailed information on their system (Textbox 1).

Note: Core diabetes self-management, CGM, and CSII education remains essential with the use of DIY AID.
CGM, continuous glucose monitoring; *CR*, carbohydrate ratio; *CSII*, continuous subcutaneous insulin infusion; *DIY AID*, do-it-yourself automated insulin delivery; *PWD*, person with diabetes; *T1D*, type 1 diabetes.

system to set higher temporary basal increases more quickly following a meal bolus [11]. For challenges with high fat/protein meals, or responses to high and low glycemic index foods, the carbohydrate absorption time can be adjusted during the bolus entry, allowing the system to adjust accordingly. Users can track "carbohydrate on board" within their app (Figure 4). PWD should be reminded to follow mealtime bolus recommendations, unless adjusting for exercise or pending hypoglycemia; they should consider that bolus recommendations consider multiple factors, including previous insulin adjustments and future predictions. For safety, the system will not recommend a bolus if current or predicted glucose is below the suspend threshold. While users are encouraged to enter carbohydrate intake into the system [6], some PWD are able to utilize autocorrections and basal adjustments to cover individual varying amounts of carbohydrate. Some users may choose to log carbohydrate entries for hypoglycemia, but this is not required [3].

Physical activity and exercise: To maximize the potential for effectiveness, exercise management strategies with DIY AID should include adjusting the system target, minimizing peak insulin action during exercise, managing pre-exercise carbohydrate intake, and accounting for changes to insulin sensitivity (Table 3). Glycemic responses will vary based on the exercise type, duration, and intensity. As with all T1D therapies, PWD should be aware that exercise during times of peak insulin action increases the risk of hypoglycemia [16]. Consuming carbohydrates up to 90 minutes before exercise (i.e. "carbohydrate loading") without temporarily adjusting settings accordingly often leads to increased insulin delivery in response to rising glucose levels [6]. This contributes to increased active insulin/insulin on board during exercise, thus increasing the risk for hypoglycemia. Adjustments can be made to insulin delivery settings to account for changes in insulin sensitivity during exercise which impacts basal and bolus settings, including the insulin sensitivity factor. The strategies outlined in Table 3 should be adapted based on individual circumstances, glucose patterns, and experiences with exercise.

Varying insulin requirements: In some situations, automated delivery adjustments may be sufficient to meet the needs of transient changes in insulin requirements, but this may not always be the case. In a recent qualitative study in women with T1D using DIY AID systems, most reported requiring additional adjustments according to their menstrual cycle [17]. In situations when automation alone is not sufficient, use of the temporary override should be discussed. Customized overrides can be saved to be used again as needed (see examples in Figure 5).

Table 3
Exercise adjustment factors to consider with DIY AID systems [2,6]

Exercise type	Glucose target	Carbohydrate management	Insulin delivery settings	Postexercise management
Aerobic exercise (e.g. walking, running, cycling, etc)	1–2 hours before exercise: set a higher glucose target	Within 3 hours of exercise: reduce carbohydrate bolus by 25%–75% 15–60 minutes before exercise: if possible/ desirable, avoid carbohydrate intake to minimize insulin on board (unless needed for pending hypoglycemia). Immediately before, at onset, and/or during exercise: consume small amounts of simple carbohydrate as needed (without entering into system)	≥1 hour before exercise: adjust temporary insulin delivery profiles to deliver ∼50% less basal and bolus insulin. Use the “Override Preset” (Loop) or adjust the “Sensitivity Ratio” (OpenAPS and AndroidAPS) to allow insulin delivery to be adjusted accordingly, including basal and bolus settings.	At completion or up to 6 hours postexercise: Cancel temporary target and changes to insulin delivery settings. Maintain adjustments up to 6 hours, if needed, to minimize post-exercise hypoglycemia. Postexercise boluses may require reduction up to 50%. Monitor glucose levels and adapt insulin delivery as needed.
Anaerobic exercise (e.g. weightlifting, sprints, strength training, etc)	Glucose targets may not require adjustment.	May not require insulin adjustments. Monitor individual patterns.		Up to 3–4 hours postexercise: consider tightening glucose targets and temporarily increasing insulin delivery profile, if needed, to avoid hyperglycemia. Consider risk of nocturnal hypoglycemia.

Note: Adapt these suggestions based on individual glycemic responses to various forms of exercise (see examples in Figure 5). Competitive and elite athletes will likely require further customized strategies.

Sensor/share: *What are the relevant characteristics of the compatible CGM sensor(s) and sharing capabilities? [10]*

The list of compatible rtCGM devices continues to evolve as sensor technology advances. Users should follow recommendations from the CGM manufacturer on calibration and confirmation CBG requirements, as applicable. Sharing capabilities are available for CGM systems via manufacturer apps. HCPs may recommend that PWD using DIY AID systems connect to Nightscout or Tidepool. These open-source cloud-based platforms provide glucose and insulin delivery metrics and daily graphs, which include CGM tracings, along with basal rate modulations, carbohydrates entered, and bolus delivered. A step-by-step approach to looking at Tidepool and Nightscout reports can be found in Table 4 and a guide to the key reports can be found in Appendices A and B.

Future Developments

When new system updates become available, it is imperative that users prioritize learning about new features. AndroidAPS

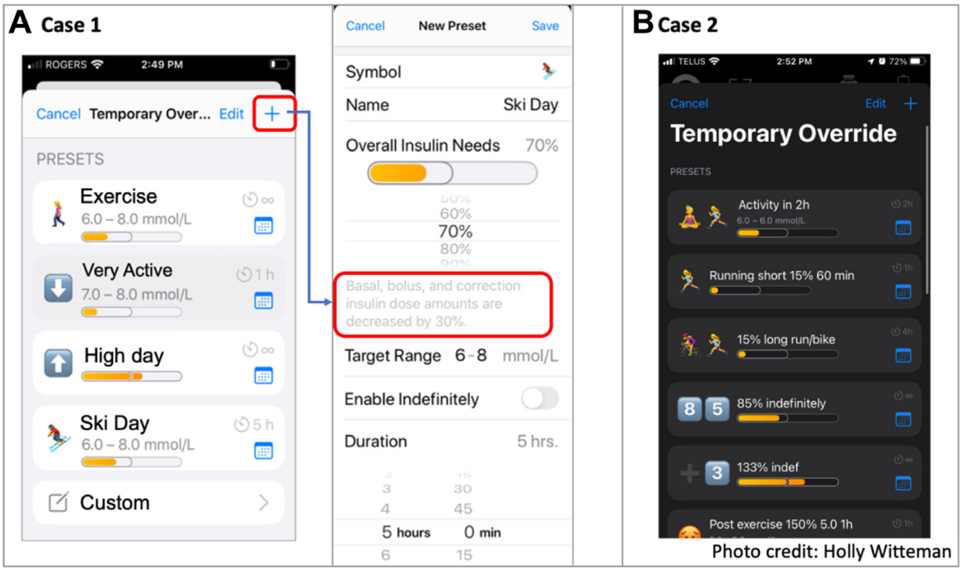


Figure 5. Customized use of the temporary override feature by Loop users. Both cases above illustrate use of multiple customized temporary override settings, including individual targets, for various activity levels. (A) Case 1 uses a 50% reduction of her overall insulin needs as a starting point to feel comfortable with most exercise. She has reduced this further for more intense activity (“Very Active” setting). She is setting up a Ski Day profile with a 30% reduction since she has learned from her patterns that she does not need to reduce as much for skiing as other activities. (B) Case 2 is an experienced Loop user who enjoys being very active. Over time, she has refined her override settings to allow her the flexibility to fit activity into her life, even after a meal, while maintaining glucose levels in her personal target range. She is able to effectively minimize her risks for hypoglycemia during exercise.

Table 4
Approach to accessing data for review during a clinical encounter

Steps	Nightscout tab	Tidepool tab
1. Insulin delivery settings	Profiles	Device settings (not currently available with Loop)
2. CGM metrics	Distribution	Basics or trends
3. Ambulatory glucose profile "Graphical View"	Percentile chart	Trends
4. Daily graph of CGM and insulin delivery	Day to day	Daily

CGM, continuous glucose monitoring.

systems require users to complete training modules with each system update. For other systems, users should read the updated documentation on their system-specific resource site (Textbox 1).

As new versions of AID DIY systems are developed, HCPs are encouraged to continue applying the CARES paradigm to facilitate ongoing understanding and to allow for continued support for PWD who choose to use these systems.

Frequently Asked Questions

How is safety maintained when people are downloading "code" from the internet without regulatory approval?

The developers of these systems are themselves living with T1D or they are caregivers of someone with T1D. Safety and avoidance of hypoglycemia is the primary objective. The open-source documents detail that users build the systems at their own risk and that all updates to the system will be tested with volunteers. PWD should stay engaged with the community to ensure they are aware of any suggested safety updates and are encouraged to upgrade their software to include the newer updates to the algorithm.

If a PWD has an adverse event (severe hypoglycemia, diabetic ketoacidosis) while using these systems, can I be found negligent/liable if I have supported them?

People with T1D have no choice but to manage their condition with life-sustaining insulin therapy that comes with an inherent risk of severe complications. It is the responsibility of the HCP to educate PWD and ensure they have the skills necessary to avoid these complications by monitoring and adjusting their insulin, glucose levels, and ketones, when necessary, regardless of the method of insulin delivery (commercial AID, basal/bolus therapy, insulin pump therapy with/without CGM, etc). To our knowledge, DIY AID has never been tested in the Canadian courts, so we can only provide the advice that all methods of insulin delivery carry the same risks, and HCP support and education are critical to ensuring safe outcomes.

Can I refuse to support PWD using a technology I am not comfortable with?

If an HCP is confronted with something outside their scope, they have an obligation to inform the individual it is not in their scope of practice and to refer on. That being said, HCPs who care for people with diabetes should make themselves familiar with all treatments available for both T1D and T2D to the best of their ability. It may not be realistic for HCPs who have low volumes of T1D in their practice to become experts in AID, and referral to someone with more expertise can and should be considered within the confines of provincial resources. It should be expected that if an HCP provides support for individuals with T1D who use commercial AID systems, they should provide similar support to a person who chooses DIY AID.

Is there a risk of using an out of warranty pump to deliver insulin?

All technology has a risk of failure. When a pump is in warranty, the company has an obligation to replace it; after the warranty has expired, this obligation is no longer enforceable under law, though many pump manufacturers will provide a loaner pump for some duration of time to bridge the individual until new funding is available. In some provinces and territories, the warranty duration is shorter than funding cycles for new pumps, meaning many PWD will be using an out-of-warranty pump regardless of the AID system they choose to use. All PWD should have a backup plan with an understanding of how to transition back to open-loop if a CGM fails or MDI if the pump fails, again, regardless of the AID system they choose.

How can I view the insulin and glucose sensor data from the PWD in my practice who are on DIY AID?

Nightscout is an open-source solution developed by PWD that provides browser-based visualization for DIY AID users. It allows retrospective analysis and remote monitoring which help facilitate HCP interactions.

Tidepool is a free platform that allows DIY loop users to upload their glucose, carbohydrate, and insulin delivery data to their account and share their data with their clinician.

What happens if the PWD does not have their phone or goes "offline"?

The algorithm uses Bluetooth technology to communicate between the CGM, the phone, and the pump, so, as long as the phone is on, the PWD does not need access to the internet for AID to continue. If the phone dies or is left at home, the PWD will continue to receive insulin based on their programmed basal rates. They should monitor glucose levels more closely since the system will not adjust delivery to prevent hypo- or hyperglycemia.

What if CGM readings are inaccurate for a time period; how will this impact insulin delivery?

Similar to those using commercial AID, PWD should be encouraged to perform a fingerstick glucose reading any time their symptoms do not match their sensor readings. CGM low and high alerts should be used, including snooze/repeat times, to prompt PWD to take action and problem solve when sensor glucose is reading in the hypo- and hyperglycemic ranges. Delivery settings should be set appropriately (Table 1) to minimize the potential for excessive over or under delivery of insulin. If the sensor is not reading accurately, closed-loop functionality should be temporarily turned off until the sensor has been replaced. Some PWD choose to use third-party adaptors that convert intermittently scanned CGM into rtCGM to enable AID; there is an added level of uncertainty with accuracy and reliability in these cases and PWD should be encouraged to fingerstick regularly.

Supplementary Material

To access the supplementary material accompanying this article, visit the online version of the *Canadian Journal of Diabetes* at www.canadianjournalofdiabetes.com.

Author Disclosures

I.J.H. has received speaker and advisory board fees from Dexcom Canada, Abbott Diabetes Canada and Sanofi unrelated to the current work; H.O.W is funded by a Canada Research Chair in Human-Centred Digital Health, has lived with type 1 diabetes since 1983, and has used a DIY AID since 2019; A.C. has received speaker fees from Dexcom Canada, Abbott Diabetes Canada, consulting fees from Dexcom Canada, and insulin pump training fees from Insulet, Medtronic and Tandem, she lives with type 1 diabetes and has personal experience using both DIY AID and commercially available AID systems (Medtronic and Tandem); P.S. is supported by the Charles A. Allard Chair in Diabetes Research and the Alberta Academic Medicine and Health Services Plan and has received personal fees for consulting for Vertex, Novo Nordisk and Viatris; K.F. is a member of the Nightscout Foundation board of directors; A.E.M. has no conflicts.

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Appendix A: Tidepool Key Report Guide (for Loop)

Tidepool use tips [3]:

- Users will need to install the Tidepool Mobile app on their phone, create an account, and follow the steps on LoopDocs (below). CGM, insulin delivery, carbohydrate data, and notes will sync without the need for an uploader.
- To view Tidepool reports on a computer, the **Chrome** web browser must be used.
- If data is not visible at first, ensure the user has entered a note in their Tidepool Mobile app.
- Loop settings are not visible in the Device Settings report, since this information cannot be uploaded from Apple Health. To obtain device settings, ask users to show you or capture screenshots of their device settings directly from their Loop app.

For additional information on using Tidepool with Loop, including options to set up a clinic account, visit: https://loopkit.github.io/looptips/data/tidepool.

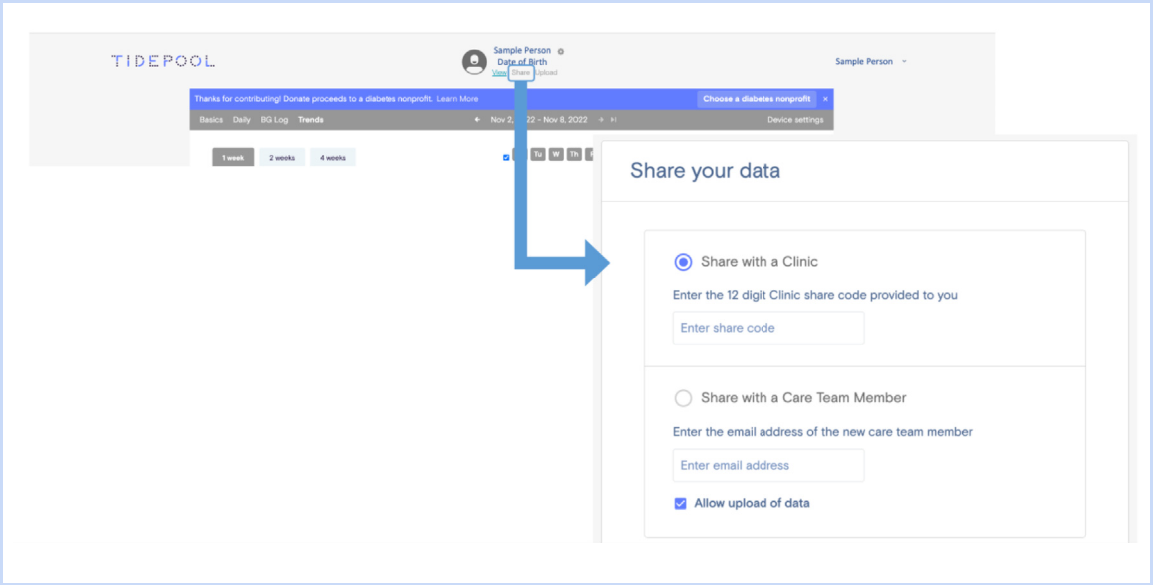
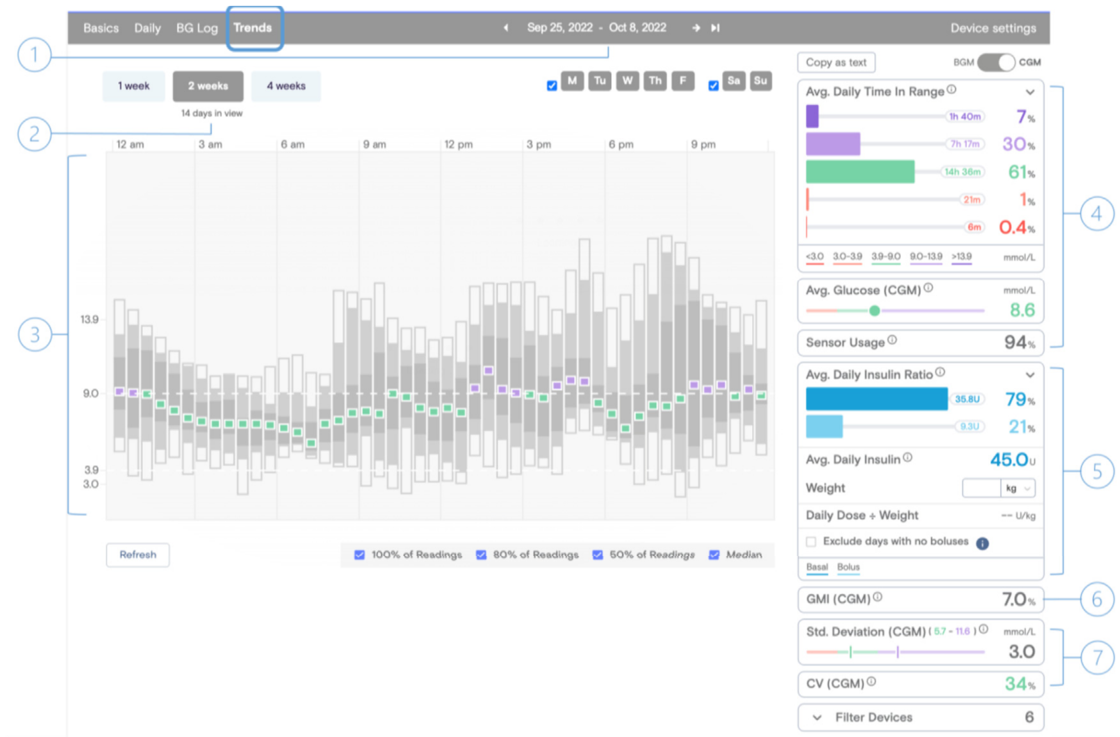


Figure A1. Sharing data with a clinic.



Report Item	Considerations & Targets*
1. Date Range	Confirm that selected dates are reflective of typical patterns. Consider potential impact of recent illness, therapy changes, activity level changes, and/or phase of the menstrual cycle.
2. Data Duration	Aim for assessing at least 2 weeks of data.
3. Glucose Trend Graph	Can view the median and/or 50%-80%-100% of readings. Examine the width and shape of the glucose trend curve. Explore which times of day have more/less time below, within, and above target ranges, and more/less glycemic variability.
4. CGM Glucose Metrics	Targets: >70% time in range (3.9-10.0 mmol/L) <4% total time below range (<3.9 mmol/L), including <1% time below 3.0 mmol/L <25% time above range (>10.0 mmol/L), including <5% time above 13.9 mmol/L *Note: Users may change their time in range parameters, such as in the above example, which is set for a tighter time in target range of 3.9-9.0 mmol/L.*
5. Insulin Delivery Metrics	Assess TDD and basal:bolus split. When basal is >50%, explore carbohydrate intake patterns and bolus behaviours.
6. Glucose Management Indicator (GMI)	Approximate A1C based on CGM readings. Target: ≤7.0%
7. Glycemic Variability Metrics	Coefficient of Variation (% CV) Target: ≤36%. Lower %CV has been associated with reduced rates of hypoglycemia.

Figure A2. Tidepool trends report. *A1C*, glycated hemoglobin; *BG*, blood glucose; *CGM*, continuous glucose monitoring; *TDD*, total daily dose. * Recommended targets from the International Consensus Report for most individuals with type 1 diabetes. Individualize glycemic goals based on individual goals and circumstances, and for special populations (pregnancy, children/adolescents, older/high-risk groups).

Key Report Items
1. Glucose Graph: Displays CGM glucose tracing for selected day (white lines indicate the customizable target range).
2. Bolus and Carbohydrates: Displays the carbohydrates entries (yellow circles) and bolus entries (blue bars).
3. Basal Delivery: Displays scheduled basal rates (dotted line) and basal modulations.
4. Glucose, Insulin Delivery, and Carbohydrate Metrics: Data summary for the selected 24-hour period.

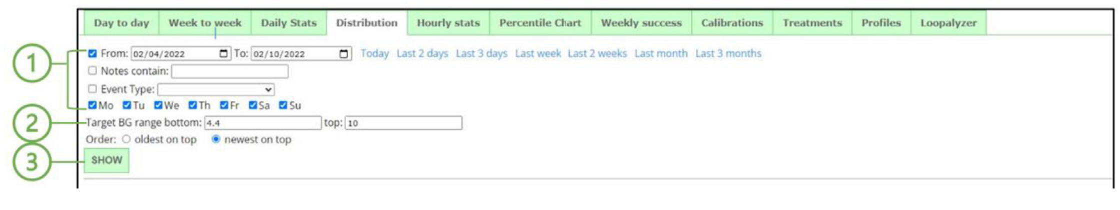
Figure A3. Tidepool daily report.

Appendix B: Nightscout Key Report Guide

Nightscout use tips:

- Users will need to create a Nightscout account and follow the set-up instructions in the documentation for their specific system (Table 1).
- Nightscout allows for real-time remote monitoring and review of multiple reports.
- Users can share their individual web address to share their data.
- To view reports from the real-time data home screen, click on the drop-down main menu (top right), and choose REPORTS.

More information on Nightscout is available at: https://nightscout.github.io.

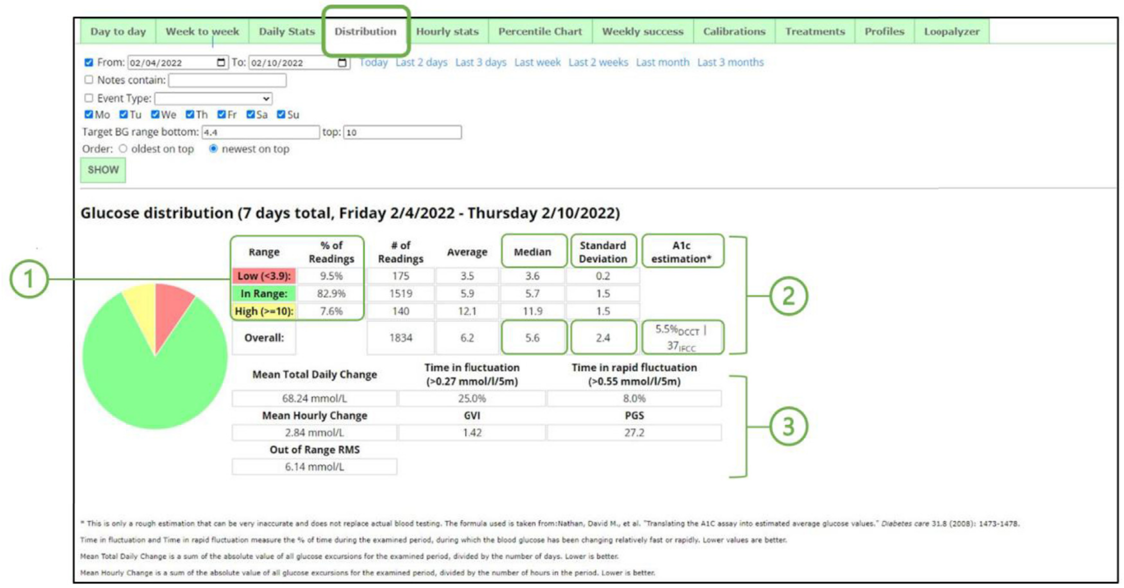


1. **Date Range** (and days of the week to include)**:** Aim for assessing at least 2 weeks of data. Confirm that selected dates are reflective of typical patterns. Consider potential impact of recent illness, therapy changes, activity level changes, and/or phase of the menstrual cycle.

2. **Glucose Target:** Confirm that targets are set to reflect the individual goals.

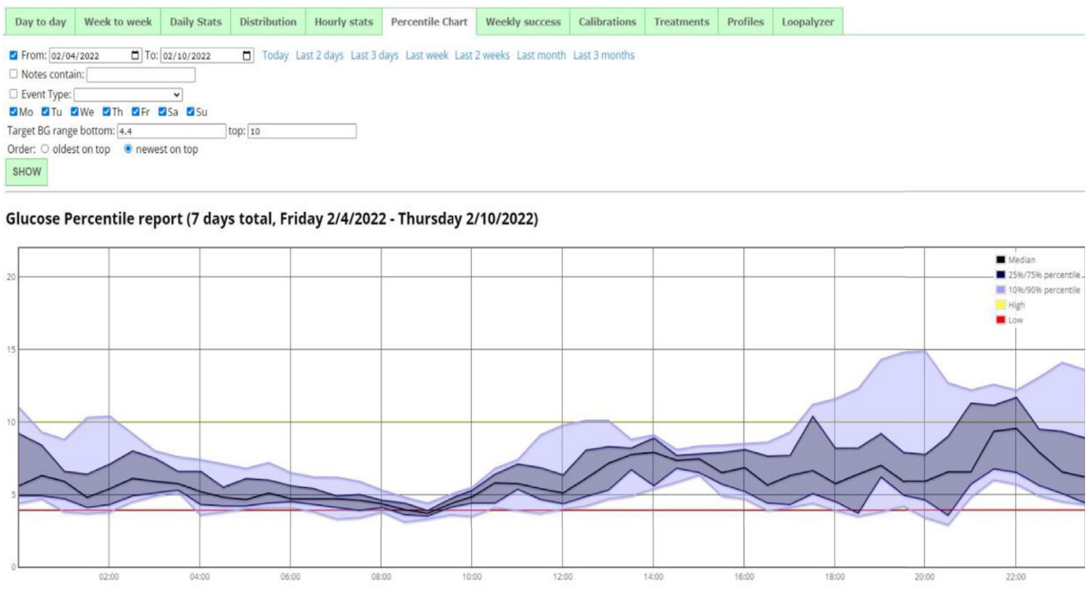
3. **SHOW:** Users must click here to generate reports.

Figure B1. Navigating the Nightscout report settings.



Report Item	Considerations
1. Time in Range Metrics	Aim for assessing at least 2 weeks of data. Confirm that selected dates are reflective of typical patterns. Consider potential impact of recent illness, therapy changes, activity level changes, and/or phase of the menstrual cycle.
2. Additional Glucose Metrics	Median glucose and standard deviation are listed by glucose range, and overall. A1C is estimated from the data selected.
3. Glycemic Variability Measures	GVI (Glycemic Variability Index) and PGS (Patient Glycemic Status) are measures of glycemic variability. Descriptions are available from Nightscout here: https://nightscout.github.io/nightscout/reports/

Figure B2. Nightscout distribution report.

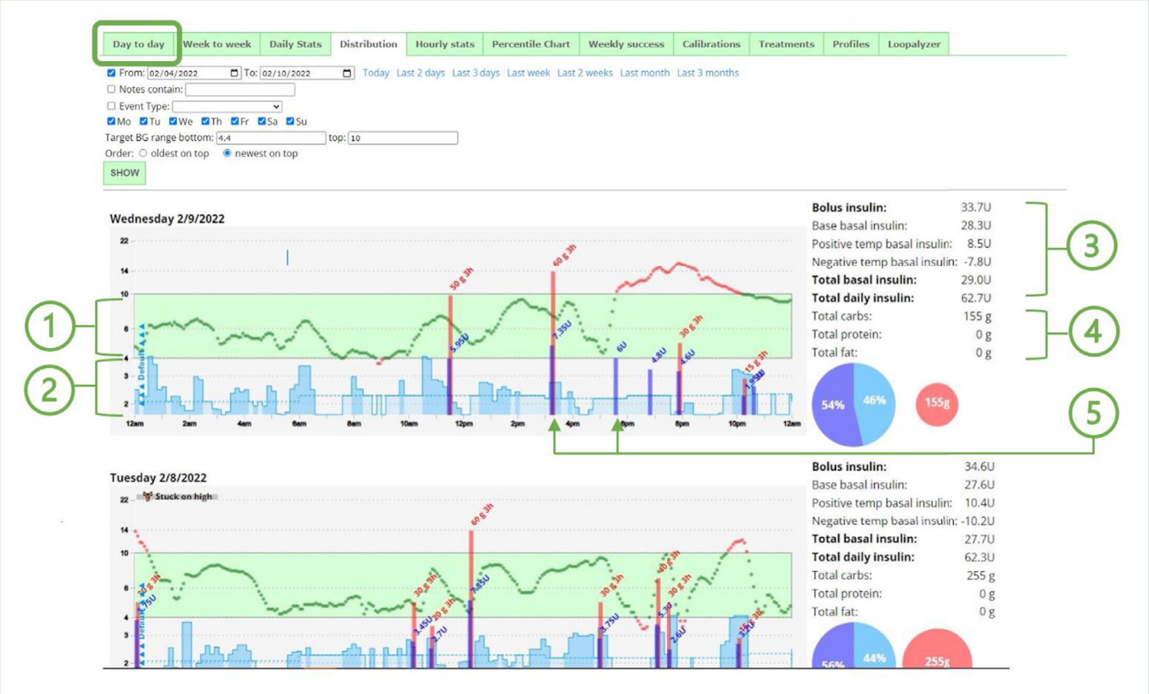


Report Tips:

Users can adjust the target glucose range before clicking “Show.”

Examine the width and shape of the glucose trend curve. Explore which times of day have more/less time below, within, and above target ranges, and more/less glycemic variability.

Figure B3. Nightscout percentile chart report.



Key Report Items:

1. CGM Glucose Tracing: Displays CGM glucose tracing for selected day (green shaded area indicates the customizable target range).

2. Insulin Delivery with Basal Modulations: Displays scheduled basal rates (blue line) and basal modulations (light blue bars).

3. Insulin Delivery Summary: Totals basal and bolus insulin delivery for the 24-hour period, including comparison of "base basal" (programmed basal rates) to actual amount of basal insulin delivered.

4. Food Intake Summary: Total carbohydrate entered for the 24-hour period, with option for protein and fat (if applicable with tools the PWD chooses to use).

5. Bolus Delivery: Purple bars indicate bolus doses, with or without carbohydrate. Additional red bars indicate carbohydrate inputs, including user selected carbohydrate absorption time.

***Tip:** On the graphs and corresponding pie charts, **light blue** indicates **basal** insulin, **dark purple** indicates **bolus** insulin, and **red** indicates carbohydrate.*

Figure B4. Nightscout day-to-day report.

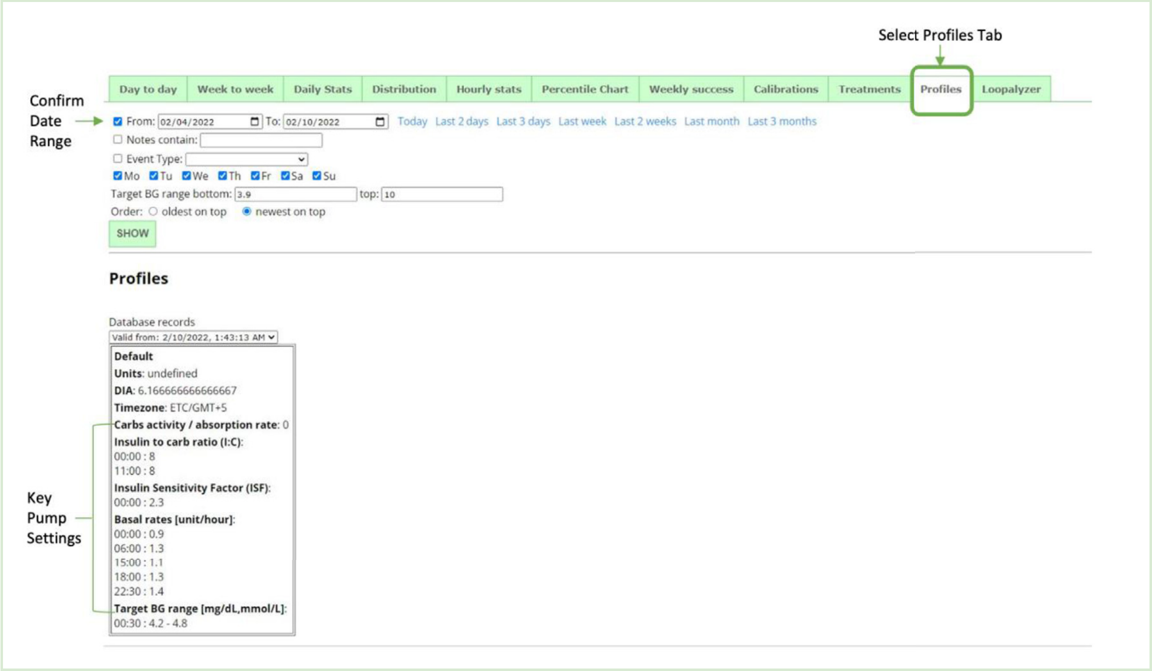


Figure B5. Nightscout profiles report.