Tidepool Loop v1.0: Anticipated Changes to DIY Loop

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Audience:

1) Tidepool Employees
2) Tidepool Loop Medical Advisory Committee
3) FDA - for review prior to, and discussion at our June 17, 2019 pre-submission meeting
4) Public - as with all Tidepool Loop documentation, this document will be made publicly available once it is ready for submission to the FDA. Tidepool welcomes feedback from the FDA, industry and the public directly via this document or by email: loop@tidepool.org.

Background and Overview

The purpose of this document is to describe the known revisions to DIY Loop for the development of Tidepool Loop. Some revisions are going to be needed in the first public version of Tidepool Loop (v1.0) and other revisions are anticipated in subsequent versions. The scope of this narrative is limited to Tidepool Loop v1.0 and does not cover the specific processes through which revisions beyond v1.0 will be validated.

DIY Loop has been a volunteer, community supported project for the last 3+ years. DIY Loop has tracked issues and feature requests in GitHub, a public platform where all users and developers can collaborate and communicate. Many improvements to DIY Loop have been made based on community-reported bug reports, user experience issues, and feature requests. Some feature requests and design changes have not been made due in large part to the lack of "staff" to do all the requested or desired work. Some feature requests can be repetitive themes on a common issue (such as how to adjust in situations where underlying insulin needs may have suddenly changed, like exercise, illness, or medications). A summary of the issues in DIY Loop's Github and development history can be found in this analysis.

Based on a review of DIY Loop, there are known issues that Tidepool considers necessary to address in its first version (v1.0) of Tidepool Loop before it is made available as an iOS application in the Apple App Store. There are other design features that Tidepool anticipates adding in subsequent versions (v1.1 or 2.0, for example) as user data and feedback is studied.

Anticipated Changes from DIY Loop to Tidepool Loop v1.0 (to be made prior to submission to FDA and for Apple review)

Loop Settings

- As appropriate, add min and/or max limits, and in some cases low and/or high warnings (details provided in the Plan for Demonstrating Safety of Tidepool Loop 1.0):
    - Correction Range (including Override Targets)
    - Suspend Threshold
    - Basal Rates
    - Insulin Sensitivity Factors
    - Carbohydrate Ratios
    - Suspend Threshold
    - Max Bolus
    - Rationale: Provides medically appropriate guardrails for Tidepool Loop settings.
- Loop settings (as listed above) will be required prior to pairing with an insulin pump.
    - For new Tidepool Loop users, Loop settings will be introduced sequentially and in a guided manner upon initial sign up or login, rather than only being discoverable in the Loop's app Settings section.
- Eliminate Walsh curve insulin model
    - Rationale: Safety. Walsh curve does not reflect reality, and allows people to enter shorter DIAs (e.g. 2 hours) which are not real.
- Eliminate Fiasp curve insulin model
    - Rationale: Fiasp is not currently indicated for use in insulin pumps.
- Saving of Tidepool Loop settings into the user's Tidepool account
    - Rationale: User experience improvement so that settings are not lost if phone is lost or reset, or app is accidentally deleted.

Services Integrations

- Add integration to Tidepool cloud data storage, making data available in Tidepool Web, Tidepool Mobile and Tidepool Loop Follow apps.
    - Rationale: Tidepool will be providing cloud storage, as well as secondary web and mobile views of Tidepool Loop data. Note per prior discussions with FDA, retrospective review is classified as Class-I/Exempt, and real-time secondary display is classified as Class-II/Exempt.
- Add mechanism to invite followers who can view user's Loop data in a retrospective or real-time secondary display
- Eliminate Nightscout, Loggly, and Amplitude integrations
    - Rationale: Tidepool will not be validating or supporting these integrations that are currently available to DIY Loop users.

Sign Up and Log In

- Add ability to create a Tidepool account in Tidepool Loop setup, or log in to Tidepool Loop using an existing Tidepool account.
- Add prescription code entry
- Add Terms of Use, Privacy Policy, and device and data privacy permissions

Invite and Manage Followers

- Tidepool Loop will have a real-time secondary display companion app called Tidepool Follow. Tidepool Loop users will be able to invite and manage follower access from the Tidepool Loop app.
    - Rationale: In DIY Loop, caregivers are able to follow their PwDs in real time with the Nightscout app. As discussed above in “Service Integrations,” Tidepool Loop will not include a connection to Nightscout. However, we do intend to replace that with a real-time secondary display Tidepool Follow app.

Issue Reporting

- Eliminate existing DIY Loop Issue Report
- Add in-app Adverse Event / MDR screening and reporting menu
    - Rationale: Collect all the same info as DIY Issue report, but also add Adverse Event information.
    - See "Extreme Post-market Surveillance and Radical Transparency" section of "Plan for Demonstrating Safety of Tidepool Loop 1.0"
- Add links to Tidepool Support and Tidepool Digital Learning Library
    - Rationale: In-app links to online support and help resources.

Device Integrations

- Addition of ACE pump and iCGM device setup for each compatible device

Apple Watch

- Autofill the bolus amount to 100% of the recommended amount (currently defaults to 75%)
    - Rationale: Inconsistent with phone user experience.

RileyLink

- All RileyLink screens will be eliminated
    - Rationale: RileyLink no longer necessary with Tidepool Loop.

Main Display

- Add visualization of bolus in progress to status bar and ability to cancel bolus with one tap (currently in DIY Loop's 1.10.0dev and omnipod-testing branches)
    - Rationale: An often requested feature that improves safety - makes it easier to cancel an in-progress bolus.

Retrospective Correction

- Retrospective correction will be permanently enabled within the algorithm; the on/off toggle will be eliminated from the UI
    - Rationale: The DIY Loop support team expects a majority of users have this enabled. Results from Jaeb Loop Observational Study will demonstrate safety.

Carbohydrate Entries

- Tidepool Loop will restrict carbohydrate reading from Apple Health to Loop-entered values only. This will prevent Loop from unintentionally treating carbohydrate entries from third-party applications such as MyFitnessPal or other food-tracking applications.
    - Rationale: Safety. Prevents inadvertent insulin delivery due to Apple Health carb entries.
- The lollipop icon's default absorption time will be shortened from the existing 2-hour duration.
    - Rationale: Fast-acting low treatments have closer to a 30 minute duration. Changing the lollipop icon's default time to closer to a low treatment duration will improve the predicted BG curve by decaying carbs on board more quickly, aligning with actual behavior of fast-acting carbs.

Code Customizations

There are 9 common code customizations offered for users of DIY Loop in LoopDocs. Tidepool Loop users will not be able to apply these code customizations.

User preferences learned from two commonly used code customizations will be incorporated into Tidepool Loop v1.0. They are described in this document under Apple Watch - Autofill the bolus amount to 100% of the recommended amount - and Carbohydrate entries - The lollipop icon's default absorption time will be shortened from the existing 2-hour duration to 30-min duration.

- The other code customizations documented in LoopDocs for DIY Loop users will not be supported in Tidepool Loop v1.0.

Insulin Delay

- Tidepool Loop will not include insulin delay, which is available in certain branches of individual DIY Loop users, but is not available in the official mainline DIY Loop repository.

In-app Orientation

- Tidepool may decide at a later time, based on results from human factors testing, to include orientation messaging in app for first time users

Cosmetic Branding and Visual Design Changes

- Tidepool may choose to make no-risk, minor, cosmetic changes to the User Experience so that Tidepool Loop is easily differentiated from DIY Loop.

Verification and Validation of These Changes

All features, whether originating in DIY Loop or Tidepool Loop, undergo quality assurance testing in accordance with Tidepool's quality management system to ensure that they work as intended. Please refer to: Tidepool Loop Verification and Validation Plan.