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Protocol DRAFT

Human Factors Validation study for Tidepool Loop Mobile Application

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Introduction

Tidepool has developed the Tidepool Loop mobile application system, including the Tidepool Loop mobile application (Tidepool Loop), a user guide, and various training resources available in-app, (collectively, the Product). Tidepool Loop is an interoperable automated glycemic controller (iAGC) device capable of automated insulin dosing when used with a compatible integrated continuous glucose monitor (iCGM) and alternate controller enabled (ACE) designated insulin pump. The Product will be available for use on iOS mobile devices, including an optional Apple Watch interface.

In order to use the Product, patients must be prescribed Tidepool Loop from a healthcare provider (HCP). Using the Product also requires therapy settings to be established with the help of an HCP. HCPs may use a web portal to enter app therapy settings for the patient, or can send the same information to Tidepool via facsimile, and Tidepool will enter the therapy settings on the HCP's behalf. Once therapy settings have been entered, the patient will receive an access code to start using the Product. The focus of this protocol will be the lay user-facing mobile application only; the HCP web portal and associated HCP training materials are considered out of scope.

Tidepool Loop's validation test plan is constructed systematically, and builds upon the (1) formative real-world history of iteration and response within the do-it-yourself (DIY) Loop project, (2) the process outputs from task and known use error analyses performed by Tidepool, and (3) the formative evaluations performed by Tidepool, and jointly by Tidepool and Core Human Factors.

The purpose of this protocol is to describe the conduct of the Human Factors (HF) Validation Study to assess whether the Product user interface maximizes the likelihood that the Product is safe and effective when used by the intended users, for the Product's intended uses, in the intended use environments.

This protocol is prepared in accordance with FDA Guidance:

- Applying Human Factors and Usability Engineering to Medical Devices (February 3, 2016)[1]

Both observational and subjective feedback data will be used to confirm whether intended users can safely and effectively perform all critical tasks associated with use of the Product.

Approach to interoperability

[1] Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices

The Product has been designed with interoperability as an objective (See e.g. FDA's "Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices" Guidance (September, 2017)[2], and "FDA authorizes first interoperable, automated insulin dosing controller designed to allow more choices for patients looking to customize their individual diabetes management device system" (December 13, 2019)[3]). Tidepool intends to provide a detailed strategy for ensuring that connected devices meet our specifications, and that appropriate risk management,verification, and validation activities for each connected device are conducted. The Product's use related risk analysis will be updated to include all new features and additional connected devices. Use related risk analyses will be conducted prior to the addition of a new feature or the integration of an additional interoperable device, and will be updated in response to postmarket surveillance. Tidepool will review the use related risk analysis to determine the impact of the new feature or additional connected device to the list of known critical tasks. For each update, Tidepool will determine if it:

1. Introduces a new critical task
2. Impacts an existing critical task
3. Requires additional usability data to understand impact to critical tasks
4. Does not impact of add any critical tasks

Subsequently, Tidepool will evaluate and validate any changes to critical tasks through design verification and Human Factors validation efforts as required. Tidepool will update labeling and training to include information on how users can connect with new or updated compatible connected devices. Tidepool's approach to validation and interoperability is based on the reevaluation of critical tasks per device integration that are affected by the changes for additional devices.

For the purposes of this Human Factors study, if a critical task involves information, such as an error state, from a connected device, the Product will simulate connection to the representative interoperable technologies, i.e., Omnipod insulin pump and the Dexcom G6 continuous glucose monitoring system. Details on these devices can be found in the public decision summaries.

[2] Available at:
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-considerations-and-pre-market-submission-recommendations-interoperable-medical-devices
[3] Available at:
https://www.fda.gov/news-events/press-announcements/fda-authorizes-first-interoperable-automated-insulin-dosing-controller-designed-allow-more-choices

Description of Intended Users, Uses, Use Environments and Training

Intended Users

The Product is intended for use by two user groups: adult users and pediatric users. Adults will be people diagnosed with Type 1 Diabetes (T1D) or caregivers of diagnosed pediatric patients. Pediatric users will be people with T1D who are responsible for managing some or all of their diabetes care independently. Users are expected to represent a range of experience with insulin pumps, CGMs and iOS devices. All users would be willing to use an app to help manage their diabetes.

For a complete description of the intended users, including an analysis of how their attributes influence Product use and how the intended users will be represented in the study, see Table 4 and Table 5 below.

Intended Uses

The Product includes an iOS app that communicates with a user's compatible Bluetooth Low Energy (LE) connected iCGM to monitor interstitial glucose levels and ACE designated insulin pump in order to deliver insulin. The Product allows for automated basal insulin delivery based on information provided by iCGM and ACE pump, as well as inputs provided by the user (e.g., carbohydrate intake, and pre-meal and workout targets). The user must program basal delivery rates and other therapy settings using the Product. The user must also input and deliver meal and correction boluses, and can use the values calculated using the Product's integrated bolus recommendation tool.

Intended Use Environment

Since the Product is meant to be used continuously, it may be used in a variety of environments. For example, patients use the Product while at home, work, a doctor's office, or other public space. The difference between environments is not expected to impact use of the Product.

For a complete description of the intended use environment, including an analysis of how its attributes influence Product use and how the environment will be represented in the study, see Table 3 below.

Intended Training

Tidepool expects all users will be trained prior to first-time use of the Product. All users must complete in-app online tutorial training provided by Tidepool before using the Product for the first time. Throughout training there are several checkpoints that serve as knowledge checks that the user must complete successfully to be permitted to proceed with training.

Tidepool's user training plan provides resources for various types of users including new pump users, users switching from a different pump to a compatible partner ACE pump, and users upgrading from a partner pump without Tidepool Loop to the same or similar partner ACE pump with Tidepool Loop. Depending on a given user's prior experience with the compatible insulin pump, their training may also include supplemental live (in-person or remote) pump training with a Certified Pump Trainer (CPT) or online training modules, as required and provided by the pump device partner.

Description of Device User Interface

Graphical Representation and Description of User Interface

Graphical and pictorial representations of Tidepool Loop screens and Apple Watch interface are presented below. The actual, intend-to-market Product components will be tested in the HF Validation study and images will be included in the final study report.

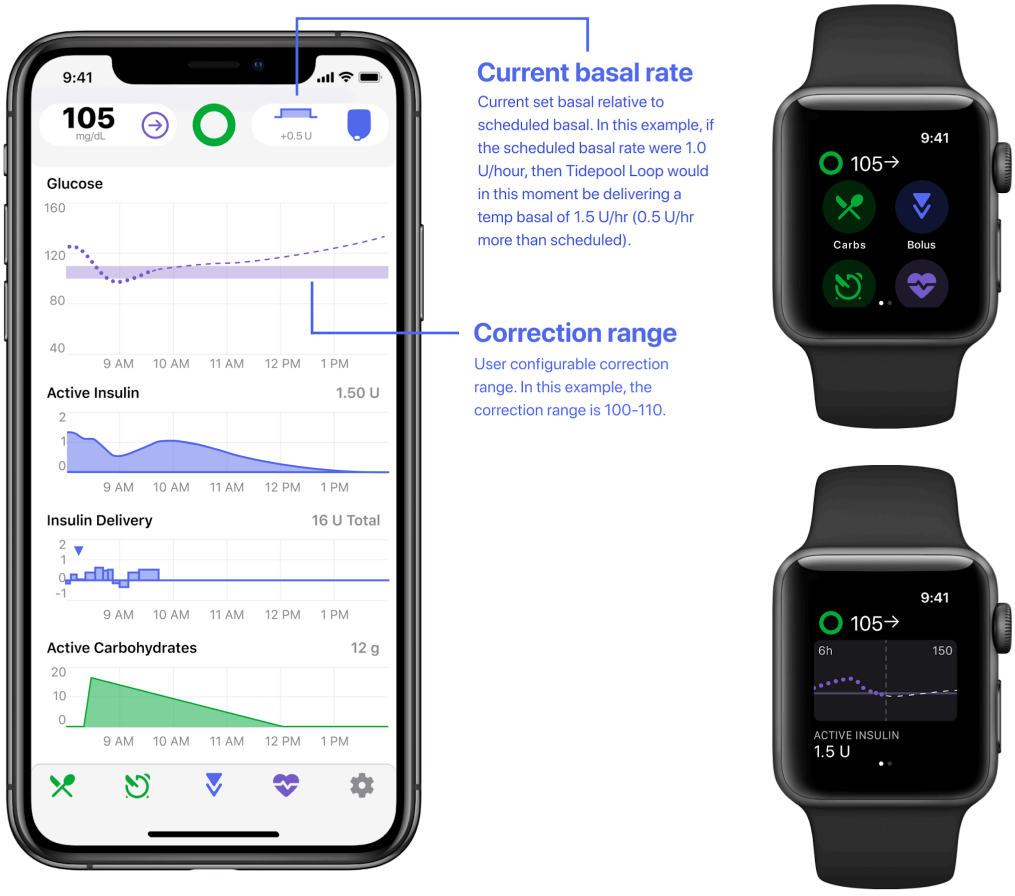

Figure 1: Home screen of the Tidepool app (left), Apple Watch menu (right, top), Apple Watch data visualization (right, bottom)

Overview of Operation Sequence

This section summarizes the steps necessary for using the Product.[4]

After receiving a prescription for the Product from a healthcare professional, the user must download Tidepool Loop from the App Store onto their mobile device and set up a Tidepool account. Following account set-up, all users must complete the in-app training tutorial. Users who do not have previous experience using insulin pumps will also receive supplemental, live (in-person or remote) pump training with a Certified Pump Trainer (CPT) or online training modules as required and provided by the pump device partner. Once training is complete, users will enter the access code received via their HCP, then review and input settings, including insulin delivery rates/limits, therapy settings, notifications, and workout and pre-meal temporary correction ranges.

In order to use Tidepool Loop, the user must prepare their ACE insulin pump and iCGM, and pair them with Tidepool Loop. A user may have a separate controller or display device for the ACE insulin pump or iCGM, and instructions will be provided on how to disconnect or uninstall separate controllers or display devices as required by the Product.

Throughout the day, the user should enter carbohydrate intake and deliver boluses accordingly, as well as deliver correction boluses as needed, using the Product. The user should continue to maintain their ACE insulin pump and iCGM, including changing device components when necessary, such as refilling pump reservoirs, replacing iCGM sensors, etc.

When they occur, the user must perceive and address a range of alarms/alerts. For example, alarms/alerts may include pump-related alerts, sensor-related alerts, and system status changes and errors.

Users also have the option of using Tidepool Loop with an Apple Watch. The watch interface allows users to input carbohydrate entries, bolus and set temporary presets for “pre-meal” or “workout” modes. Additionally, the watch can also be used as a secondary display to view glucose data.

Summary of Known Use Problems

Tidepool is using incident data from sources such as database searches recommended by FDA guidance to learn about known use-related problems associated with devices comparable to the Product in terms of the intended users, use environments, and/or uses.

[4] For a comprehensive list of all steps, see the Tidepool Loop Use-Related Risk Analysis (URRA), available in Tidepool’s online QMS at [TBD]

In addition, Tidepool expanded this analysis to include reports from members of online social media community groups used by the DIY Loop community. Reports from social media group participants provide insight into real world use of DIY Loop. This data is used as an input to Tidepool's risk analysis and to inform specific design mitigations to mitigate the known problems. Tidepool's final Summary of Known Use Problems Report will be submitted with our Human Factors Engineering/Usability Engineering (HFE/UE) Summary report and will also describe design controls that Tidepool implemented as risk control measures for the known problems identified during this analysis.

A search for known use issues with DIY Loop was performed by Tidepool to identify use problems that may be relevant to the Product. The investigation period extended as far back in time as practical for the source data, (e.g. four weeks for Facebook post data, and several years for GitHub issues). Problems occurring recently are likely to have the greatest relevance because they are likely to involve the most comparable user experience and characteristics.

The search consisted of user-reported issues from the DIY Loop Facebook community from December 29, 2019 to January 28, 2020. In addition, DIY Loop users were asked to report use issues via an online survey. Tidepool collected English-language responses from a survey from January 14, 2020 until the last collected response, January 29, 2020. Responses and reports were then examined for use errors and any event of interest related to a use problem associated with the device. The authors identified and analyzed reports, and made assertions/interpretations regarding the root cause.

The search for user-reported issues in GitHub targeted all issues on the DIY Loop project spanning from October 18th, 2018 to January 12, 2020. The authors identified and analyzed the remaining issue reports to attempt to ascertain the root cause.

As a result of the analysis of Looped Facebook posts, the DIY Loop user survey and the analysis of DIY Loop Github issues, the following 57 types of known problems were identified. A summary of known use problems of DIY Loop including potential root causes, is provided below. The final Summary of Known Use Problems Report of all analysis will be submitted in our HFE/UE report.

Description of known use problem
ABSORPTION TIME CONFUSION: User observes the bolus recommendation is less than expected for a medium or long absorption carb entry. User confusion.
ACCIDENTAL USER INPUT: User unintentionally inputs or changes a setting. User reports hyperglycemia or hypoglycemia.
ACTIVE CARBS CONFUSION: User is uncertain of accuracy of active carbohydrates. User does not comprehend if appropriate to delete, edit or leave carb entries.

ACTIVE INSULIN INACCURATE AFTER PUMP / SITE FAILURE: Due to hardware or pump site failure, active insulin is inaccurate. User does not comprehend how to take appropriate action. User confusion.
INAPPROPRIATE THERAPY SETTINGS: User observes adjustment of temp basal that is not effective in lowering glucose values to the correction range. User reports hyperglycemia.
INAPPROPRIATE THERAPY SETTINGS: User observes temp basal increases and reports hypoglycemia.
TEMP BASAL ADJUSTMENTS UI CONFUSION: User does not comprehend that temp basal adjustments are displayed relative to scheduled basal rates. User does not comprehend how much basal insulin is being delivered or has been delivered. Device design. User confusion.
AUTOMATED INSULIN DELIVERY CONFUSION: Users report not understanding periods of suspension or lowered basal delivery when current sensor glucose is below correction range and glucose prediction is above correction target range. User confusion.
BOLUS RECOMMENDATION CONFUSION: Users report not understanding 0 U bolus recommendation after carb entry. Users do not comprehend Active Insulin impact on bolus recommendation. User confusion.
MISSED MEAL INPUT CARB DATE/TIME ENTRY ERROR: User inputs a carb entry for a missed meal but does not adjust the time of the carb entry which could lead to inappropriate/higher bolus recommendation.
INCORRECT CGM TRANSMITTER ID: User does not update CGM transmitter ID. CGM data does not display. Loss of use.
THERAPY SETTINGS DECIMAL POINT INPUT ERROR: Use error during manual number input for carbohydrate ratio setting. User inputs 0.8 instead of 8.0. User receives overdelivery of insulin.
DELIVERY LIMIT CONFUSION: User assumed temp basals were limited to 2x scheduled basal. User reported 4x scheduled basal delivered. User misinterpreted max basal delivery limit setting. User confusion.
DEXCOM SHARE GLUCOSE DATA: User observes difference in Loop glucose data compared to retroactively smoothed glucose data in Dexcom SHARE app. User confusion
DUPLICATE CARB ENTRY: User inadvertently adds duplicate carb entry. User misinterprets carb entry and bolus as part of one continuous flow. Device design.
FIASP USE: User mixes fiasp with regular fast acting insulin and reports issues with high glucose after meals. Foreseeable misuse.
GLUCOSE CHANGE SHOWS NO CARB ABSORPTION IN ABSENCE OF SENSOR GLUCOSE DATA: User reports consuming carbs to treat hypoglycemia. User checks Glucose Change chart in Carbohydrates screen. User reports seeing "0g absorbed" and consumes additional carbs to address hypoglycemia resulting in hyperglycemia later. User does not understand that the Glucose Change chart requires sensor glucose data to display approximation and visualization of carb absorption. User confusion. Device design.
ALGORITHM / GLUCOSE MOMENTUM CONFUSION: User reports not understanding a situation where without three recent points of glucose data (due to unreliable CGM data)

glucose momentum is not used. User confusion.
GLUCOSE PREDICTION CONFUSION/INAPPROPRIATE ACTION: User misinterprets the calculated eventual glucose and glucose prediction visualization. Consequently, user reports taking action to deliver insulin or consume carbohydrates resulting in hyperglycemia or hypoglycemia, especially when the eventual glucose value is very high or very low.
CONFIGURATION OF WORKOUT / PRE-MEAL: User has not configured correction range for pre-meal or workout modes. User does not understand why the toolbar icons are disabled. Device design.
MAX BASAL SET HIGH TO AVOID BOLUSING: User intentionally sets max basal limits very high in an effort to not bolus using Loop. User receives overdelivery after inaccurate carb count or lost connection with app. User reported low glucose. Foreseeable misuse.
HIGH TEMP DURING BOLUS: User inputs carbs and delivers a large bolus. User observes high temp basal adjustment during the bolus resulting in high active insulin on board. User reported low glucose.
ABSORPTION TIME CONFUSION: User inputs carb entry for meal with higher fat intake. User misinterprets how to handle higher fat intake meals and adjust carb absorption time. User delivers recommended bolus. User reported hypoglycemia.
EDIT CARB ENTRY: User estimates carbs for unknown meal. The user did not update carb entry with additional carb intake. User reported hyperglycemia.
EXOGENOUS INSULIN: User injects a bolus in addition to pump insulin. Active insulin and glucose prediction do not account for exogenous insulin delivery. and glucose prediction.
TOTAL INSULIN DELIVERY UI CONFUSION: User misinterprets value on insulin delivery chart as active insulin (IOB) instead of total insulin delivered since midnight. Informational density and insufficient visual hierarchy. Device design.
PUMP PAIRING CONFUSION: User is interrupted during pump pairing flow and is unsure whether to tap the "continue" button. Device design.
RETRIEVAL OF SETTINGS AFTER PHONE FAILURE OR REPLACEMENT: User therapy settings are stored locally. User is unable to retrieve therapy settings after phone failure/replacement. User confusion.
COMMUNICATION ERROR DURING CARB ENTRY AND BOLUS: User entered carbs and lost connection with device before attempting to bolus. User did see or comprehend the error and did not notice the lost connection until later. User reported hyperglycemia.
TEMPORARY BASAL ADJUSTMENT AFTER LOSS OF CONNECTIVITY: User does not understand that automation requires continuous connectivity between pump and controller. Temp basal adjustment continues for 30 minutes before returning to scheduled basal. User reports overdelivery or underdelivery of insulin. User confusion.
BOLUS RECOMMENDATION CONFUSION: User observed the app suspending basal insulin after carb intake/entry and bolus. User reported confusion of bolus recommendation amount. User does not comprehend observed changes in glucose impact on temp basal adjustments.

NO ALERT/WARNING FOR MAX BOLUS ON BOLUS RECOMMENDATION User reported bolus recommendation does not display alert or warning that recommendation is limited by max bolus limit. User expects alert/warning to be presented in Loop. User confusion.
MEDICATION IMPACTS INSULIN / GLUCOSE: User reported taking medication that impacted insulin sensitivity.
ACTIVE INSULIN IMPACT ON INSULIN DOSING: User reported manually suspended insulin delivery for two hours. User reported negative active insulin after resuming insulin delivery. User reported high temp basal after resuming insulin and low glucose.
APPLE HEALTH PERMISSION: User did not comprehend how to enable write permissions for Loop to Apple Health.
0 U BOLUS RECOMMENDATION WITH NO SENSOR GLUCOSE DATA: User receives no glucose prediction and 0 U bolus recommendation when no CGM data is present. User reported hyperglycemia. User confusion on how to receive bolus recommendation without sensor glucose data.
NOTIFICATION FOR CORRECTION BOLUS: User expects to receive a notification when app recommends a correction bolus. Feature request.
OTHER PUMP SYSTEM CONFUSION: User reported confusion on differences between familiar diabetes management strategies and terminology from other pump systems familiar and Loop. User confusion on how to translate the desired treatment strategy to actions and settings in Loop.
OVERRIDE CONFUSION: User does not understand “Overrides” impact on therapy settings, insulin requirements, bolus recommendations or glucose prediction. User reports overdelivery or underdelivery of insulin.
RESERVOIR VOLUME: User expects Loop to report reservoir values for a pump. Loop only reports value when reservoir total is under 50 units for Omnipod. User confusion.
PENDING INSULIN CONFUSION: User reported observation of "pending" insulin on bolus screen UI. User does not understand if they should deliver pending insulin amount or bolus recommendation amount. User confusion. Informational density. Device design.
MAINTAIN PHONE BATTERY: User does not keep the phone charged. User does not receive glucose data, alerts, or alarms or automation of insulin delivery. Inappropriate insulin dosage. Scheduled basal resumes.
PUMP EXPIRATION CONFUSION: User does not understand how long insulin delivery will continue after expiration alarm. User confusion.
BOLUS RECOMMENDATION When determining whether or not to recommend a bolus for carbohydrates entered if all of the predicted glucose values are above the threshold, Loop will recommend a bolus even if the current glucose is below the threshold.
SUSPEND/RESUME INSULIN DELIVERY: User forgets to resume insulin delivery.
CONNECTIVITY RF ENVIRONMENT INTERFERENCE: User observes interruption between phone and diabetes device communication in particular buildings and environments.
THERAPY SETTINGS CONFUSION: User attempts to adjust settings to troubleshoot performance. Potentially inappropriate therapy settings. User confusion.

SETTINGS ENTRY ERROR: User unintentionally added therapy setting for a range or time period in an incorrect order and app crashed. Delay in therapy.
SETTINGS UI NAVIGATION: User is unable to find a desired system setting. Informational density. Insufficient visual hierarchy. Device design.
SYSTEM TIME CHANGE: User changes system date or time on phone either manually or automatically by changing time-zones, resulting in time discrepancies that impact CGM, insulin delivery, glucose prediction.
TIME ZONE CHANGE USER CONFUSION - User observed glucose correction range and other time based settings are not automatically updated when user travels to a different timezone. User did not understand how to change time zone offset manually after travel.
UI CONFUSION: User does not comprehend how to edit a setting. User doesn't perceive the gesture or tap target as actionable. Device design.
UI CONFUSION: User does not comprehend how to edit a setting or does not comprehend iconography. User doesn't perceive the gesture or tap target as actionable. Device design.
DETECT AND MANAGE INACCURATE/UNRELIABLE ICGM FUNCTION: User does not understand how to detect and manage inaccurate/unreliable cgm function - e.g. check BG if sensor readings do not match user's symptoms, user does not understand whether to turn off automation (toggle Closed Loop mode off).
IOS SETTINGS CONNECTIVITY CONFUSION: User misinterprets problems with connectivity issues. User thinks problems are due to low power mode iOS setting.
DO NOT DISTURB MODE ALERTS IMPACT: User does not see, hear or feel notification/alert/alarm due to "'Do not Disturb" mode. Loop Failure alert state at 20, 40, 60 and 120 minutes not detected. User does not take action.
BOLUS RECOMMENDATION CONFUSION: User does not understand 0 U bolus recommendation after carb entry. User does not understand suspend threshold impact on glucose prediction and bolus recommendations.

Analysis of Hazards and Risks Associated with Use of the Product

The tasks and steps that must be completed to successfully use the Product are described in the URRA. The URRA identifies as critical tasks any task which, if performed incorrectly or not at all, could lead to serious harm, where harm is defined to include compromised medical care. Tidepool has identified any task with a potential harm associated with severity 3 or higher as a critical task. The definition of the severity scale used to rate potential harms is provided below in Table 1. For each severity score, the table includes a general description of the hazard severity, as well as criteria for mapping the outputs of the Tidepool Risk Severity Evaluation Tool (TRSET) to the appropriate score for scenarios in which the TRSET is used. For any scenario

evaluated by the TRSET, two metrics are measured - the Diabetic Ketoacidosis Index (DKAI) and the Low Blood Glucose Index (LBGI).

Table 1: Severity rating scale

Severity Score	Criteria for TRSET outputs (where applicable)	Category	Description
4	DKAI ≥ 21 hrs	Critical	The person with diabetes likely has Beta-Hydroxybutyrate (BHB) present in their blood at a level (>4.4 mmol/L) that indicates that they are in Diabetic Ketoacidosis (DKA), though the severity of the DKA could vary between mild, moderate, and severe.
	LBGI > 10		The person with diabetes experiences a hypoglycemic event resulting in death, permanent impairment, or life-threatening injury.
			The hazard results in user death, permanent impairment, or life-threatening injury
3	14 ≤ DKAI < 21 hrs	Serious	The person with diabetes likely has BHB present in their blood at a level (>3.0 mmol/L) that indicates they are likely, though not certainly in DKA.
	5 < LBGI ≤ 10		The person with diabetes experiences a hypoglycemic event that results in injury or impairment requiring medical intervention, including administration of IV fluids.
			The hazard results in injury or impairment requiring medical intervention, including administration of IV fluids
2	8 ≤ DKAI < 14 hrs	Minor	The person with diabetes likely has BHB present in their blood at a level (BHB > 1.8 mmol/L) that requires monitoring, but is only a minor risk of DKA.
	2.5 < LBGI ≤ 5		The person with diabetes experiences a hypoglycemic event that results in temporary injury or impairment not requiring medical intervention.
			The hazard results in temporary injury or impairment not requiring medical intervention.
1	2 ≤ DKAI < 8 hrs	Negligible	The person with diabetes likely has BHB present in their blood at a level (<1.8 mmol/L) that is not likely to be DKA.
	LBGI ≤ 2.5		The person with diabetes experiences a hypoglycemic event that results in inconvenience or

			temporary discomfort.
			The hazard results in inconvenience or temporary discomfort.
0	DKAI < 2 hrs	None	The person with diabetes likely has BHB present in their blood at a level (<0.6 mmol/L) that indicates they are not in DKA.
	LBGI = 0		The person with diabetes does not experience a hypoglycemic event.
			The hazard does not cause a harm.

The critical tasks, their associated subtasks, hazards and severity of potential harm are listed in Table 2.[5]

Table 2: Critical task list

Task	Subtask	Hazard Associated with Potential Use Errors	Severity
(Setup task) Proceed through onboarding and complete In-app tutorial training	Complete in-app Tidepool Loop tutorial and onboarding	User is not aware of how to properly operate Tidepool Loop Inappropriate dosage of insulin.	4
	Proceed through in-app Tidepool Loop tutorial and onboarding and toggle on Closed Loop On mode	User does not toggle Closed Loop mode on Automation of insulin delivery does not start System/pump uses user-defined settings	3
Entering and editing Therapy Settings - Workout Temp Adjust	Navigate to Therapy Settings management screen Tap Temporary Correction Ranges	User unintentionally edits Workout Temp Adjust mode Inappropriate dosage of Insulin	3
	Edit Workout Temp Adjust	User sets an inappropriate Workout Temp Adjust mode Inappropriate dosage of insulin	3

[5] For a comprehensive list of tasks (both critical and non-critical) and their associated hazards, harms, and severity ratings, see the Tidepool Loop URRA, available in Tidepool's online QMS at [TBD]

	Taps Save	User does not save edits to Workout temp adjust mode Inappropriate dosage of insulin	3
Entering and editing Therapy Settings - Carb Ratio	Navigates to Therapy Settings management screen Tap Carb Ratio	User unintentionally edits carb ratios Inappropriate dosage of insulin	3
	Edits Carb Ratio	User adds inappropriate carb ratios Inappropriate dosage of insulin	3
	Taps Save	User does not save edits to carb ratio User confusion and inappropriate dosage of insulin	3
Identify and review current sensor glucose reading	Understand current sensor glucose	User cannot read or misinterprets displayed glucose value on app display User misinterprets glucose chart and other glucose data on app display User confusion Inappropriate dosage of insulin	3
Understand Glucose Prediction	Understand glucose prediction	User misinterprets glucose prediction on Home Screen User takes inappropriate action based on misinterpretation of glucose prediction Inappropriate dosage of insulin	3
Review glucose prediction for hypoglycemia	Comprehend predicted glucose	User cannot read or misinterprets displayed glucose value on app display User misinterprets glucose chart and other glucose data on app display	3
Enter Carbs and Bolus	Add Carbohydrates Entry Taps Carb Entry icon	User does not understand how to navigate to Add Carb Entry screen User confusion	3

		User does not take action	
	Enters Amount consumed	User incorrectly inputs or incorrectly estimates carb entry amount Inappropriate dosage of insulin	3
	Reviews recommended bolus and inputs amount to bolus	User inappropriately overrides bolus recommendation Inappropriate dosage of insulin	3
	Confirms bolus - User can use FaceID, TouchID or passcode.	User does not comprehend how to confirm and deliver bolus Inappropriate dosage of insulin	3
Stop Bolus in progress	Taps the Stop icon on temporary status banner while a bolus is in progress	User does not stop an unintended bolus in progress Inappropriate dosage of insulin	4
Edit Carb Entry	Navigate to Carb Entries screen	User does not understand how to navigate to Carb Entries screen User does not understand how to edit Carb Entry Inappropriate dosage of insulin	3
	Edit Amount of Carbs	User incorrectly edits amount of carbs Inappropriate dosage of insulin	3
	Taps Save	User does not save edits User confusion	3
Enable Workout Temp Adjust	Toggle on Workout Temp Adjust	User does not comprehend need to use Workout temp adjust mode or change settings during periods of temporary insulin sensitivity Inappropriate dosage of Insulin	3
	User comprehends if Workout Temp Adjust is enabled.	User enables Workout temp adjust mode indefinitely - user forgets to toggle off after use, or physical activity User accidentally disables (toggles off)	3

		Workout temp adjust mode User accidentally enables (toggles on) Workout temp adjust mode Inappropriate dosage of insulin	
Understand Tidepool Loop status indicator	Views Tidepool Loop status indicator	User does not see or misinterprets Tidepool Loop status User will not receive automation of insulin delivery, may receive inappropriate insulin dosage, and scheduled basal resumes	3
	Views current error	User does not see or detect, does not comprehend Tidepool Loop status indicator error state User does not comprehend how to tap the CGM sensor status icon to determine iCGM status	3
	User detects/comprehends automation of insulin delivery currently happening	User does not troubleshoot system User will not receive automation of insulin delivery, may receive inappropriate insulin dosage, and scheduled basal resumes	3
Add blood glucose reading and deliver recommended bolus	Navigates to blood glucose entry on bolus screen Taps on prompt to enter blood glucose reading	User does not comprehend 0U bolus recommendation in absence of current glucose values User does not add a manual BG entry to receive a recommendation User overrides 0U recommendation and delivers inappropriate dosage of insulin Inappropriate dosage of insulin	4
	Enter BG value and taps continue	User enters incorrect blood glucose (BG) value	4

		Inappropriate delivery of insulin	
	Inputs amount to bolus	User inappropriately overrides bolus recommendation User delivers recommended bolus based on incorrect carbohydrate value Inappropriate dosage of insulin	3
	Confirms bolus - User can use FaceID, TouchID or passcode	User does not comprehend how to confirm and deliver bolus Inappropriate dosage of insulin	3
Manually suspend insulin delivery	Tap Suspend Insulin	User unintentionally suspends insulin delivery	4
Resume insulin delivery after manual suspension	Tap Resume Insulin on the temporary banner on the Home Screen or Navigate to Pump Status/Settings screen and Tap Resume Insulin	User forgets to resume insulin Inappropriate dosage of insulin Tidepool Loop can not complete automation	4
Launch app after phone restart	Launches the app after user restarts their phone	User does not launch Tidepool Loop after restarting smart device User will not receive glucose data, alerts, or alarms or automation of insulin delivery Inappropriate insulin dosage Scheduled basal resumes	3
Respond to alert or alarm	Comprehend and dismiss notification	Dismiss notification without comprehending notification's content. User does not respond to notification. One alert/alarm will be unique to Tidepool Loop ("Loop Failure"), and consequently will be included for assessment. As the content of all other alerts/alarms were previously assessed in partner device validation, assessment of this alarm is expected to adequately evaluate whether the format/presentation of alarms support comprehension of previously validated content.	3
Does not change treatment behaviors	Does not change existing behaviors to treat high glucose and accounts	User does not detect or treat unexplained high glucose.	3

(Hyperglycemia)	for adjustments already made by Tidepool Loop	Inappropriate dosage of insulin	
Does not change treatment behaviors (Hypoglycemia)	Does not change existing behaviors to treat low glucose	User does not detect or treat low glucose. Inappropriate dosage of insulin	4
Management of low glucose (< 70 mg/dL)	Adjusting settings to prevent	Inappropriate dosage of insulin	3
Watch Tasks			
Maintain connectivity between Apple Watch and iOS smart device and connected iCGM and ACE Pump devices	[Knowledge Task] Knows when to use Tidepool Loop on an Apple Watch. User comprehends that watch can not be used with Tidepool Loop without proximity to phone	User leaves smart device (iPhone) behind and expects to receive alerts/alarms, CGM data, and automated insulin delivery via Apple Watch.	3
Enter Carbs and Bolus	Taps Carb Entry icon	User does not understand how to navigate to the Add Carb Entry screen User not using full potential of Tidepool Loop	3
	Enter Amount Consumed	User incorrectly inputs/selects by rotating Digital Crown/pressing + or -, incorrectly estimates carb amount or does not input carb entry for carbs consumed Inappropriate dosage of insulin	3
	Review Bolus Recommendation and input Bolus amount	User overrides recommended bolus Inappropriate dosage of insulin.	3
	Confirms Bolus	User does not comprehend how to confirm and deliver bolus entry by rotating Digital Crown Inappropriate dosage of insulin	3

Enable Workout Temp Adjust	Toggle on Workout Temp Adjust	User does not comprehend need to use Workout temp adjust mode or change settings during periods of temporary insulin sensitivity User accidentally disables (toggles off) Workout temp adjust mode Inappropriate dosage of Insulin	3

Summary of Preliminary Analyses and Evaluations

Formative evaluation methods

A summary of preliminary analyses and evaluations of Tidepool Loop is provided below. The final Summary of Preliminary Analyses and Evaluations will be submitted in our HFE/UE Report.

Building on the formative work of the real-world history of iteration and response within the DIY Loop project, and the process outputs from known use error analyses, Tidepool has evaluated Tidepool Loop using the following methods:

Expert reviews. UI design was evaluated at two stages in the design process by Human Factors teams of Tidepool's device partners. The first review took place when the system was in the preliminary design phase.

Usability tests. On five occasions, Tidepool has conducted usability tests of the evolving Tidepool Loop UI. A total of 23 test sessions served to identify Tidepool Loop's UI strengths and opportunities for improvement.

Tidepool will also be completing subsequent formative evaluations in addition to a dry-run of our validation test plan with a focus on a nearly production-equivalent prototype.

The table below summarizes the method, and key findings and related design modifications of our usability testing.

Date	Software	Description of identified risk	Participants	Findings	Design modifications
2019-11-24	Usability Testing Tidepool Loop app Device Status Bar - CGM Display, Pump Display,	CGM Display, Pump Display, Navigation, Device Status/Age Impacted by proposed changes	4 total All CGM/Pump experienced and DIY Loop experienced.	All participants observed "Pod Age" status icon had been removed from Home Screen. Each participant shared similar user stories for how they rely on it when handing off care for children or planning their days. CGM	Sensor and pump age indicators added to Home and Device Status Screens

	Navigation, Device Status / Age	and device integrations		Status Icons and Pod Status Icons were made more distinct by moving the Tidepool Loop status indicator from the left to the middle.	Tidepool Loop status indicator moved to center
2020-02-13	Usability Testing Tidepool Loop app Combined Carb Entry and Bolus Flow	Carb/Bolus entry User inadvertently creates a duplicate carb entry. After a carb entry, the user does not understand the 0 U bolus recommendation presented. User inputs additional carb entries in order to produce a bolus recommendation. User does not understand impact of predicted glucose on bolus recommendation. Impacted by proposed changes	5 total 3 Adult PwD's; 4 caregivers of children with diabetes All CGM/Pump experienced and DIY Loop experienced	All participants understood the real-time glucose preview of carb effect, and combined carb and bolus effect on predicted glucose. The users also were able to understand how to change bolus amounts and view the updated prediction. All participants noticed the mitigation of double carb entry risk, especially caregivers of children with diabetes. Several participants were concerned about the loss of active insulin (IOB) and active carbs values on the bolus screen as participants described that they use these numbers to check DIY Loop's bolus recommendation.	Consider glucose chart prediction label Consider replacing Active Insulin and Active Carbs on bolus screen.
2020-04-03	Tidepool Loop app Device Status Bar	Device Status Bar indicator Interpreting device life, insulin volume, planning device changes Impacted by proposed changes and device integrations	5 total All CGM/Pump experienced and DIY Loop experienced DIY Loop experienced and naive People with diabetes and	Preference was demonstrated for indicators filling in from left to right. This felt more intuitive to participants than emptying from right to left. The participants were able to navigate from home screen device status bar to the more detailed device status screens and cards. All participants were able to navigate from the device status icons "pills" to the respective device status screens. All participants had difficulty	Further design iterations with age status indicator bars progress Exploration of incremented bars Exploration of indicators presented only in the remaining 24hrs of the device life

			caregivers	understanding pump status icon grace period after 72 hours.	Exploration of instructional content around pod expiration, grace period
2020-04-24	Tidepool Loop Device Status Bar	Device Status Bar indicator Interpreting device status and age, insulin volume, planning device changes Impacted by proposed changes and device integrations	5 total All CGM/Pump experienced DIY Loop experienced and naive People with diabetes and caregivers	All participants were able to anticipate the direction of device age indicator, understand time remaining on devices in order to make decisions based on how to plan to replace their devices around a complex schedule. There was a slight preference for indicators to always be present on Home Screen, for incremented indicators, and for an explicit countdown of the grace period. All but one participant could identify and comprehend Total insulin from midnight value on Insulin Delivery chart, although no participants felt it was valuable on the home screen. All participants supported explicit explanation of running out of insulin as a potential cause of a pod ending earlier than expected.	Sensor and pump age indicators from left to right over time UI acceptance of sensor and pump status icon indicators and CGM and Pump status screens Consider replacing Total Insulin on Insulin Delivery Chart on Home screen Add instructional content to warning on device age to indicate insulin reservoir implications on device age
2020-05-15	Usability Testing Tidepool Loop app Glucose Chart	Glucose chart User misinterprets current, past, or predicted glucose Impacted by proposed changes	4 total All CGM/Pump experienced Mix of DIY Loop experienced and naive People with diabetes and caregivers	Across each prototype, all participants were able to understand: - Current glucose values - Glucose history - Predicted glucose - Prediction changes with each new data point - Y axis capping at 40-400 mg/dL was similar to how Dexcom presents glucose data - The red and yellow regions represented user defined high and low thresholds	Visualize high and low glucose thresholds Remove or repurpose "Eventually" label for more actionable time horizon.

				- Far future prediction was not likely to come true	Cap prediction Y axis at 0-440 mg/dL. Further iteration and usability testing needed to evaluate potential impact of design control on discoverability of data entry error through magnitude provided by very high and very low predictions.

Details of Human Factors Validation Testing

Overview

Participants who are representative of the intended users of the Product will attend, via video conference, individual, simulated-use training and testing sessions conducted by study moderators. Both observational and subjective feedback data will be used to confirm whether the intended users can safely and effectively perform all critical tasks associated with use of the Product. All sessions will be conducted remotely via secure video conferencing.

During training sessions, all participants will independently complete the in-app training included with the Product. Participants representing insulin pump-naive users will receive supplemental live (in-person or remote) pump training with a Certified Pump Trainer (CPT) or online training modules provided by the device partner. In-app tutorial training sessions are expected to last up to 60 minutes. CPT training sessions or online training modules provided by the device partner are expected to last up to 120 minutes.

During testing sessions, participants will be provided a prototype of the Product in the commercially proposed form and will be engaged in a first-time use scenario designed to prompt participants to use the Product as realistically as possible. Participants' knowledge and understanding of the Product will be evaluated based on observable performance. Following simulated use, participants will be asked questions designed to test their knowledge or understanding of the Product that were not able to be evaluated by observation of performance. Participants will then be interviewed about the root cause of any observed use events, such as use errors or difficulties, that occurred during simulated use.

As a simulated-use study, participants will not be administering or receiving any actual medical treatment. The study product will be representative of the intend-to-market version of the Product. Participants will be presented with either a web-based interactive Figma prototype

intended to be viewed on an iPhone, or an interactive TestFlight application prototype, intended for use on an iPhone. The screen size and navigational components of both prototype options will be representative of the intended commercial product.

Rationale for Type of Test Selected

This HF Validation Study will be a simulated-use study. Actual treatment is not required to assess the Product's critical tasks. All critical tasks will be assessed through participant interaction with simulated data in the study product.

Participants will attend via video conference, individual simulated-use training and testing sessions conducted by study moderators. Participants will complete all sessions remotely by video conferencing with the study moderator. Video conferencing will be set up to allow the moderator to observe both the participant and their interactions with the study prototypes via webcam and iPhone screen sharing. All critical tasks are expected to be able to be adequately assessed via video conferencing.

Tidepool expects that a remote study is representative of expected use of Tidepool Loop. It is worth emphasizing that Tidepool Loop is based on a DIY Loop that has been used successfully by thousands of people with Type 1 diabetes and caregivers over the past 4+ years that can and do teach themselves to use at home with limited informal, digital resources and support. Tidepool also expects that remote HF validation study sessions will also offer a number of advantages including increased access that has the potential to bring a broader and more diverse set of participants during recruitment.

Additionally, due to the coronavirus pandemic, in-person sessions would pose an unnecessary risk to participant and study personnel safety.

Study Design

Participant begins when the participant signs the Informed Consent/Assent Form (see Appendix B: Informed Consent Form and Appendix C: Informed Assent Form) and ends when the subjective feedback questions are completed.

Study sessions will follow the general structure outlined below:

1. Participants sign an Informed Consent/Assent Form
2. Participants log onto the video conferencing link and troubleshoot any technical issues
3. Participants receive an introduction to the study
4. Participants are asked demographic questions
5. Participants complete in-app training and supplemental live (in-person or remote) pump training with a Certified Pump Trainer (CPT) or online training modules if representing insulin pump naive users
6. Participants complete a memory decay period of 1 hour. Tidepool expects users of Tidepool Loop to begin use of the Tidepool Loop app immediately after proceeding

through the Tidepool Loop in-app learning, as completion of the full in-app learning is intended to include the set-up of the devices which will begin automating the user's insulin delivery upon set-up. By allowing for no more than a one hour decay period between training completion and use, study participants will more closely mimic real-world use of the device.

7. Participants perform representative tasks that simulate real-life use of the Product
8. Participants answer knowledge task questions
9. Participants are interviewed for subjective feedback related to root causes for an observed or self-reported use-related issues

See Appendix D: Moderator's Guide for the detailed interview script.

Study Environment

The test environment will be the participant's home, an expected real world use environment. Table 3 outlines attributes of the Product's use environments, expected influence of these attributes on use, and how these attributes will be represented in testing sessions.

Table 3: Use-related environmental attributes

Environmental Attribute	Home Environment	Influence on Product Use	Study use environment
Lighting	Low to bright	The Product has a backlit screen that may be more difficult to see in brightly lit areas. Users are expected to adjust lighting of the room or move to an area with appropriate lighting as needed when using the Product.	Variable, depending on participant's home environment. Participants will be asked to adjust the lighting such that they would feel comfortable using their smartphone
Noise and Stress	Homes typically have ambient noise including talking from other rooms, fans/air conditioners, or audio from devices like televisions or telephones.	Distracting levels of noise may affect users' ability to perform use-related tasks	Variable, depending on participant's home environment
Temperature and Humidity	Between 65ºF to 75ºF and 20% to 50% relative humidity	No expected impact on Product use	Variable, depending on participant's home environment
Furnishings	May include a variety of home furnishings including seating and tables	No expected impact on Product use	Variable, depending on participant's home environment

Study Location

The study will take place remotely via video conference. Study participants are expected to be in their own homes, but may participate from any location of their choosing.

Study Training

Users of the Product must complete in-app training prior to using the Product, so all participants in this Human Factors Validation study will also complete this training. Tidepool expects that users without previous experience using insulin pumps who are prescribed the Product, as well as those switch pump brands in order to use the Product, would complete additional live (in-person or remote) pump training with a Certified Pump Trainer (CPT) or online training modules provided by the device partner, as required by the device partner.

In-app Training

During onboarding and in-app training, participants will receive an introduction to Tidepool Loop, instructions on how to set up and use the app and will complete several practice scenarios designed to provide a “day in the life using Tidepool Loop” experience. The onboarding and in-app training will also guide participants through device pairing example iCGM and ACE insulin pump devices.

Supplemental Insulin Pump Training

Supplemental pump training consists of live (in-person or remote) pump training with a Certified Pump Trainer (CPT) or required online or in-app training modules provided by the device partner. This training will follow the device partner’s specified pump training procedure.

Study Participants

Two user groups will be represented in the study:

1. Adult users (patients and caregivers)
2. Pediatric patients

The sections below present the use-related attributes of each of the intended user groups and how these attributes will be represented by study participants. Since the use of the Product to care for oneself or one’s child is not expected to impact how an individual uses the Product, adult patients and adult caregivers will be represented by a single, blended user group. For additional details on how participants will be screened into the study, see Appendix A: Recruiting Screener. Note that the Recruiting Screener is a guide; specific numeric targets are not requirements, and if they are not met, it does not indicate a failure to test a sample that is representative of the intended users.

Adult User Participants

Table 4: Use-related user attributes (adult users)

User Attribute	Adult Patients	Adult Caregivers	Influence on Product Use	Participants
Diagnosis	Will be diagnosed with T1D, requiring use of insulin therapy (Patients)	Will be a primary caregiver for a child diagnosed with T1D	Individuals who have been diagnosed with T1D (or are the caregiver of a diagnosed pediatric patient) are expected to understand the need for medication (insulin) delivery.	Same
Time since diagnosis	Will represent a mix of time since first diagnosis to first-use of the Product	Same as Adult Patients	Longer time since diagnosis is expected to increase familiarity and comfort with managing diabetes and insulin therapy	Same
Age	Will be a mix of ages 18 years and older	Same as Adult Patients	No expected impact except as it relates to decline in vision or dexterity, which is analyzed below	Same
Gender	Will be a mix of males and females, or non-binary.	Same as Adult Patients	No expected impact	Same
Sensory abilities	Will have a mix of sensory abilities (i.e., vision) as seen in the general population, but would not have any sensory impairment that would prevent them from using a mobile application	Same as Adult Patients	Sensory abilities may affect a user's ability to perceive written information or experience tactile feedback. In real-life, the Product does provide auditory feedback. The study device will not have auditory feedback, however the study goals are to assess comprehension only and feedback is not expected to impact study results.	Same
Experience with CGMs	Will have a mix of previous experience using CGMs	Same as Adult Patients	Previous experience using CGMs may lead to positive or negative transfer when using the Product Inexperienced users who will need to learn to use a CGM, followed by the Product, may become more easily overwhelmed.	Same
Experience with insulin pumps	Will have a mix of previous experience using insulin pumps	Same as Adult Patients	Previous experience using insulin pumps may lead to positive or negative transfer when using the Product	Same

			Inexperienced users who will need to learn to use an insulin pump, followed by the Product may become more easily overwhelmed	
Experience with iOS	Will have a mix of previous experience using iOS mobile devices	Same as Adult Patients	Inexperienced users who will need to learn to use the Product and iOS simultaneously may become more easily overwhelmed	Same
Willingness to use an app for diabetes management	Will be willing and able to use a mobile application as part of their diabetes management plan	Same as Adult Patients	Only individuals willing to use an app to help manage their diabetes would be users of the Product	Same

Pediatric Patient Participants

Table 5: Use-related user attributes (pediatric users)

User Attribute	Intended Pediatric Users	Influence on Product Use	Participants
Diagnosis	Will be diagnosed with T1D, requiring use of insulin therapy	Individuals who have been diagnosed with T1D are expected to understand the need for medication (insulin) delivery.	Same
Time since diagnosis	Will represent a mix of time since first diagnosis to first-use of the Product	Longer time since diagnosis is expected to increase familiarity and comfort with managing diabetes and insulin therapy	Same
Age	Will be a mix of ages 12-17 years The Product will be indicated for use in patients ages 2 years and above, but it is not expected patients under age 12 will use the Product independently	Increased maturity and education that comes with age is expected to improve a user's ability to use the Product	Same
Gender	Will be a mix of males and females	No expected impact	Same
Sensory abilities	Will have a mix of sensory abilities (i.e., vision) as seen in the general population, but would not have any sensory impairment that would	Sensory abilities may affect a user's ability to perceive written information or experience tactile feedback. The Product does not provide auditory feedback and as such auditory abilities have no expected impact on use	Same

	prevent them from using a mobile application		
Experience with CGMs	Will have a mix of previous experience using CGMs	Previous experience using CGMs may lead to positive or negative transfer when using the Product Inexperienced users who will need to learn to use the Product and a CGM simultaneously may become more easily overwhelmed	Same
Experience with insulin pumps	Will have a mix of previous experience using insulin pumps	Previous experience using insulin pumps may lead to positive or negative transfer when using the Product Inexperienced users who will need to learn to use the Product and an insulin pump simultaneously may become more easily overwhelmed	Same
Experience with iOS	Will have a mix of previous experience using iOS mobile devices	Inexperienced users who will need to learn to use the Product and iOS simultaneously may become more easily overwhelmed	Same
Willingness to use an app for diabetes management	Will be willing and able to use a mobile application as part of their diabetes management plan	Only individuals willing to use an app to help manage their diabetes would be users of the Product	Same
Willingness to use Product independently	Will be willing to use the Product with minimal supervision from an adult	Only individuals who would be willing (and trusted by an adult) to use the Product independently would be users of the Product	Same

Inclusion Criteria

In addition to the selection criteria described in the user attribute tables above, participants must also meet all of the following criteria:

- Have the capacity to understand study risks and consent to be in the study
- Be available and willing to participate in the study
- Be willing to be audio and video recorded during the study
- Reside in the United States
- Speak and be able to read English

Exclusion Criteria

In addition to the selection criteria described in the user attribute tables above, to be included in the study, participants must also fail to meeting any of the following exclusion criteria:

- Be trained as a healthcare professional
- Have participated in any prior studies on the Product

Sample Size

The HF Validation Study will include a minimum of 15 participants per participant group. Three extra participants per participant groups will be recruited to account for potential “no shows” and last-minute cancellations. Therefore, the total sample size may range from approximately 30 to 36 participants.

Description and Categorization of Critical Tasks

All critical tasks are presented below and will be evaluated in this study. Critical tasks have been defined as those that, if performed incorrectly or not performed at all, could result in serious harm, where harm is defined to include compromised medical care. Tidepool has categorized tasks with a severity of 3 or higher as critical tasks. Tasks will be assessed by observation of performance and/or verbal response to knowledge task questions. Critical tasks and their corresponding success criteria and Assessment IDs (that map to the Moderator’s Guide) are presented below in Table 6.

Table 6: Study tasks

Task	Subtask	Success criteria	Assessment Type	Assessment ID	Severity
(Setup task) Proceed through onboarding and complete In-app tutorial training	Completes in-app Tidepool Loop tutorial and onboarding	Completes in-app Tidepool Loop tutorial and onboarding	Observation Task	PPT	4
	Proceed through in-app Tidepool Loop tutorial and onboarding and toggle on Closed Loop On mode	Toggle on Closed Loop On mode	Observation Task	TCL	3
Entering and editing Therapy Settings - Workout Temp Adjust	Navigate to Therapy Settings management screen Tap Temporary Correction Ranges	Navigates to Workout Temp Adjust	Observation Task	SWT	3
	Edit Workout Temp Adjust	Edits Workout Temp Adjust per prescription	Observation Task	EWT	3
	Taps Save	Taps Save	Observation Task	SWS	3
Entering and editing Therapy Settings - Carb Ratio	Navigates to Therapy Settings management screen	Navigates to Carb Ratio	Observation Task	SCR	3

	Tap Carb Ratio				
	Edits Carb Ratio	Edits Carb Ratio per prescription	Observation Task	ECR	3
	Taps Save	Taps Save	Observation Task	SCS	3
Identify and review current sensor glucose reading	Understand current sensor glucose	Identifies current sensor glucose reading	Observation Task	ISG	3
Understand Glucose Prediction	Understand glucose prediction	Correctly points to or identifies glucose chart and points to glucose prediction dashed line	Observation Task	IPG	3
Review glucose prediction for hypoglycemia	Comprehend predicted glucose	Correctly identifies a predicted hypoglycemia when the glucose chart shows a hypoglycemic episode within the next thirty minutes	Observation Task	IPH	3
		Indicates that they should monitor closely and be prepared to confirm sensor glucose with a fingerstick and treat with fast-acting carbs	Knowledge Task	RPH	3
Enter Carbs and Bolus	Add Carbohydrates Entry Taps Carb Entry icon	Selects Carb Entry icon	Observation Task	ECE	3
	Enters Amount consumed	Enters Amount consumed	Observation Task	ECC	3
	Reviews recommended bolus and inputs amount to bolus	Manually enters intended amount, or taps the recommended amount	Observation Task	CBL	3
	Confirms bolus - User can use FaceID, TouchID or passcode.	Confirms bolus - User can use FaceID, TouchID or passcode.	Observation Task	CBA	3
Stop Bolus in progress	Taps the Stop icon on temporary status banner while a bolus is in progress	Taps "Stop" to halt bolus in progress in temporary banner or status bar	Observation Task	SIB	4
Edit Carb Entry	Navigate to Carb Entries screen	Taps on active carbohydrates graph to navigate to Carb Entries Screen	Observation Task	RCE	3
	Edit Amount of Carbs	Edit Amount of Carbs	Observation Task	RCE	3

	Taps Save	Taps “Save”	Observation Task	ECE	3
Enable Workout Temp Adjust	Toggle on Workout Temp Adjust	Toggle on Workout Temp Adjust	Observation Task	TWA	3
	User comprehends if Workout Temp Adjust is enabled.	Identifies where on the Home Screen (Correction range or toolbar button state) they would look to see that the mode was enabled	Observation Task	KWA	3
Understand Tidepool Loop status indicator	Views Tidepool Loop status indicator	Identifies Tidepool Loop status indicator	Observation Task	SID	3
	Views current error	Identifies how to check the glucose chart and taps the CGM status icon for more information about the recency of the glucose data and error state.	Observation Task	VCE	3
	User detects/comprehends automation of insulin delivery currently happening	Identifies automation of automated insulin delivery is not happening and indicates need to troubleshoot.	Observation Task	OFF	3
Add blood glucose reading and deliver recommended bolus	Navigates to blood glucose entry on bolus screen Taps on prompt to enter blood glucose reading	Taps on prompt to enter blood glucose reading	Observation Task	SMG	4
	Enter BG value and taps continue	Enters BG value as intended and taps “Continue”	Observation Task	EBG	4
	Inputs amount to bolus	Manually enters recommended bolus amount, or taps the recommended amount	Observation Task	SBL	3
	Confirms bolus - User can use FaceID, TouchID or passcode	Confirms bolus - User can use FaceID, TouchID or passcode.	Observation Task	CBO	3
Manually suspend insulin delivery	Tap Suspend Insulin	Taps “Suspend Insulin” and Confirms suspension of insulin	Observation Task	SSI	4
Resume insulin delivery after manual suspension	Tap Resume Insulin on the temporary banner on the Home Screen or Navigate to Pump Status/Settings screen and Tap Resume	Taps “Resume Insulin” on the temporary banner on the Home Screen or navigates to Pump Status/Settings screen and	Observation Task	RSI	4

	Insulin	taps “Resume Insulin”			
Launch app after phone restart	Launches the app after user restarts their phone	Knows to launch app again after a phone restart	Knowledge Task	LAR	3
Respond to alert or alarm	Comprehend and dismiss notification	Comprehends the Loop is in not automating insulin delivery and dismisses notification. Comprehends need to troubleshoot connectivity	Observation Task	RAL	3
Does not change treatment behaviors (Hyperglycemia)	Does not change existing behaviors to treat high glucose and accounts for adjustments already made by Tidepool Loop	Knows not to change treatment behaviors due to use of Tidepool Loop except to account for any adjustments already made by Tidepool Loop	Knowledge Task	DCH	3
Does not change treatment behaviors (Hypoglycemia)	Does not change existing behaviors to treat low glucose	Knows not to change treatment behaviors due to use of Tidepool Loop	Knowledge Task	DCL	4
Management of low glucose (< 70 mg/dL)	Adjusting settings to prevent	Knows to contact HCP and/or adjust settings with HCP	Knowledge Task	HCP	3
Watch Tasks					
Maintain connectivity between Apple Watch and iOS smart device and connected iCGM and ACE Pump devices	Knows when to use Tidepool Loop on an Apple Watch.	Comprehends that Watch can not be used with Tidepool Loop without proximity to phone	Knowledge Task	WPP	3
Enter Carbs and Bolus	Taps Carb Entry icon	Taps icon on watch to enter carbs	Observation Task	WEC	3
	Enter Amount Consumed	Inputs/selects by rotating Digital Crown/pressing + or - carb amount	Observation Task	WCA	3
	Review Bolus Recommendation and input Bolus amount	Inputs/selects bolus amount by rotating Digital Crown or by pressing + or - carb amount	Observation Task	WWB	3
	Confirms bolus	Confirms and delivers bolus entry by rotating Digital Crown	Observation Task	WCB	3
Enable Workout Temp Adjust	Toggle on Workout Temp Adjust	Toggles on Workout Temp Adjust	Observation Task	WWT	3

Subjective Feedback

Participants will be asked subjective feedback questions after being interviewed to determine the root causes of use errors, near misses, and operational difficulties. These questions are designed to ascertain participants' subjective experience using the Product.

Study Blinding

A unique identification number will be assigned to each participant as a means of participant identification, so that Tidepool will be unable to associate participants' names or identity with study data.

Data Collection and Coding

Overview

During sessions, Moderators from Core will make notes on paper or electronically of their observations of potential issues or successful completion by participants. Issues to note include instances in which participants use, almost use, or report using or almost using the Product in unexpected or unintended ways. Moderators will note both observations of participant actions that represent pre-defined usability issues for which harms have been identified and also observations of previously unanticipated use issues. The goal of coding performance is not to assess the participants; the goal is to assess the ability of the user interface to achieve a desired result.

Empirical Data: Participants will be given an opportunity to use the Product independently and in a manner that is as realistic as possible without guidance, coaching, praise, or critique from the Moderator. Data, such as successful or failed performance of tasks, will be measured directly rather than from participant opinions. The Moderator will observe participant behavior during the testing to assess participants' adherence to protocol and proper technique, and to assess and understand the nature of any use events that occur.

Subjective Data: The Moderator will ask open-ended questions of participants at the end of each scenario following the Moderator's Guide. Questions such as "Did you have any difficulty using this product? [If so] can you tell me about that?" will be asked. The questions will explore performance of tasks involved in the use of the Product and any problems encountered.

Data Scoring

Moderators will use the coding in table below to categorize their observations made in real-time during study sessions:

	Requirements

Scores	Record description of observed event	Record root cause(s)	Conduct follow-up risk analysis
S - Success	**NO**	**NO**	**NO**
Use without any assistance or any observed or reported Use Errors, Close Calls, Use Difficulties, or Artifacts.			
UE - Use Error	**YES**	**YES**	**YES**
A user action or lack of action that was different from that expected by the manufacturer and caused a result that (1) was different from the result expected by the user and (2) was not caused solely by Product failure and (3) did or could result in harm.			
CC - Close Call	**YES**	**YES**	**YES**
An instance in which a user makes a Use Error but then takes an action to "recover" and prevent the harm from occurring. This may include cases when the participant requests assistance (e.g., calling someone for help) AND appropriate/realistic assistance prevented the harm from occurring.			
UD - Use Difficulty	**YES**	**YES**	**YES**
An observed or reported difficulty other than a Use Error or Close Call. Use Difficulties include repeated attempts to complete a task, hesitating, excessive "exploring" of the user interface while expressing verbal or non-verbal cues of confusion, unexpectedly referring to the labeling before taking the correct action or commenting during the post-test interview that something was hard to do. Note that a delay that may result in harm should be scored as a Close Call or, if the delay is sufficient to cause harm, then it should be scored as a Use Error. Use Difficulties can result from user confusion and might indicate user interface features that have an increased potential to cause Use Errors for different users or under different conditions of use. The primary distinction between a Close Call and a Use Difficulty is that the potential for harm is apparent with a Close Call whereas a Use Difficulty has to cause a Use Error to in turn lead to harm.			
A - Artifact	**YES**	**YES**	**NO**
An event resulting from aspects of the simulated-use study that did not accurately represent real life. Study artifacts reduce the sample size assessed for the task.			
NA - Not Assessed	**YES**	**NO**	**NO**
A task that was not assessed. As an example, this may be due to insufficient time in the study because a participant arrived late to the study session. Tasks that are not assessed reduce the sample size assessed for the task and therefore additional testing may be warranted. This score does not apply to time-critical tasks during which the participant ran out of time.			

Probing for root cause will focus on eliciting from the participant an estimate of the root cause of the use event with reference to ways in which the Product interacts with the following human components:

- *Perception*: What does the user have to see, hear, or feel for successful performance?

- *Cognition*: What does the user have to know, understand, count, or interpret for successful performance?
- *Action*: What does the user have to manipulate, move, push, or control for successful performance?

After sessions are complete, data analysis will take place to provide conclusions about what happened in the study that represent potential real-life usage. Analysis and reporting will provide a final score to categorize study findings while leaving the initial notes and scores unchanged in the data collection sheets.

Data Collection Tools

All sessions will be audio and video recorded. A screen capture will also be recorded to capture participant's interactions with the user interface. Moderators will capture participants' behavior and verbal comments in the space provided in the Moderator's Guide. If deemed necessary, use events may be reviewed on the video recordings for further analysis.

Statistical Analysis

The purpose of this study is to identify and analyze potential use-related issues regardless of the rate of occurrence of those issues. Therefore, no quantitative hypothesis testing will be conducted; only descriptive statistics, frequency counts, and proportions may be used to summarize data.

Results

Study results will be compiled into an HF Validation Study Report that includes participant demographic information, as well as the specific use events that occurred for all tasks listed in the Moderator's Guide, the root cause of each use event, and a summary of additional task-related subjective feedback from participants. This study is also intended to identify and capture unanticipated use events. Thus, it is not limited to capturing only pre-established failure modes. Participants' comments that are not safety-related may be provided in a section of the report separate from potentially safety-related data.

Follow-up Risk Analysis

At the end of the study, Tidepool will analyze all use events involving actions or lack of actions on the part of the participants that might affect safety or efficacy under actual conditions of use. Follow-up risk analysis will include a review of all use events and their root causes. Use events include use errors, near misses, and operational difficulties. In particular, use events involving actions, or lack of actions, on part of the participant that might affect safety and efficacy under actual conditions of use will be compared to the use-related risk analysis to identify the

associated risks and determine whether these risks are acceptable, or whether additional mitigations are necessary to reduce the risk to acceptable level.

Appendix A: Recruiting Screener

Recruiting Goals

Recruit a total of 36 participants as follows:

Adult Users (18 participants)

- Patients or primary caregiver of pediatric patients
    - Diagnosed with Type 1 diabetes
- Device experience
    - Mix of experience with insulin pumps
    - Mix of experience with continuous glucose monitors
    - Mix of iOS and Android device users
- Diabetes experience
    - Mix of time since diagnosis
- Demographics
    - Mix of gender
    - Mix of ages 18+ years

Pediatric Users (18 participants)

- Patients diagnosed with Type 1 diabetes
- Device Experience
    - Mix of experience with insulin pumps
    - Mix of experience with continuous glucose monitors
    - Mix of iOS and Android device users
- Diabetes experience
    - Mix of time since diagnosis
- Demographics
    - Mix of gender
    - Mix of ages 12 to 17 years

Script

Hello. My name is _____ from _____, a research firm. We are conducting a study to evaluate a potential new medical device.

If you qualify and participate in the study, we will ask you to pretend to use the product and then ask for your feedback about it. You will only be pretending to use it, not actually using it. You will NOT be asked to take any medication. The purpose is to understand how people may use this product in real life.

[Pump experienced participants]: The study will involve you participating in two remote sessions via video chat, one day apart, to meet with a member of our research team for a

one-on-one interview. The first session will take approximately 1 hour and the second session will take approximately 2 hours. In appreciation for your time, we are offering a $_____ honorarium.

[Pump inexperienced participants]: The study will involve you participating in two remote sessions via video chat, one hour apart, to meet with a member of our research team for a one-on-one interview. The first part of the session will take approximately 3 hours and the second session will take approximately 2 hours. In appreciation for your time, we are offering a $_____ honorarium.

Would you be interested in seeing if you qualify for our study?

Text in bold/italics are instructions to the recruiter and are read aloud to the participant.

#	Questions	Rules	Quotas
General Demographics			
1	Do you/your child live in the United States?		
	a *Yes*	*Continue*	-
	b *No*	*Disqualify*	-
2	Are you/your child willing to be audio- and video- recorded for this study?		
	a *Yes*	*Continue*	-
	b *No*	*Disqualify*	-
3	Have you been professionally trained or educated as a healthcare professional?		
	a *Yes*	*Disqualify*	-
	b *No*	*Continue*	-
4	What gender do you/does your child identify as?		
	a *Male*	*Continue*	*Recruit min 2/group*
	b *Female*	*Continue*	*Recruit min 2/group*
	c *Other*	*Continue*	-
5a	*(Adult Patients/Adult Caregivers only)* What is your age? *(Record:_____)*		
	a *Under 18*	*Disqualify*	-
	b *18 to 40*	*Continue*	*Recruit min 2*
	c *40 to 65*	*Continue*	*Recruit min 2*
	d *66 and older*	*Continue*	*Recruit min 2*
5b	*(Pediatric Patients only)* What is your child's age? *(Record:_____)*		
	a *Under 12*	*Disqualify for Pediatric Pat.*	-
	b *12 to 14*	*Continue*	*Recruit min 2*

	c	*15 to 17*	*Continue*	*Recruit min 2*
	d	*18 and older*	*Disqualify*	-
6	Which of the following conditions (if any) have you/your child been diagnosed with?			
	a	Asthma	*Continue only if also "b"*	-
	b	Type 1 Diabetes	*Continue*	-
	c	Type 2 Diabetes	*Disqualify*	-
	d	Multiple Sclerosis	*Continue only if also "b"*	-
	e	Renal failure	*Continue only if also "b"*	-
7	Does your/your child's diabetes require the use of insulin therapy?			
	a	*Yes*	*Continue*	-
	b	*No*	*Disqualify*	-
7b	*(Adult Caregivers only)* How often do you assist your child with counting carbohydrates or dosing insulin?			
	a	Most of the time	*Continue*	-
	b	Some of the time	*Continue*	-
	c	Rarely	*Disqualify*	-
8	How long ago was your/your child's diabetes diagnosis?			
	a	*Less than 1 year ago*	*Continue*	*Recruit min 1/group*
	b	*1-2 years ago*	*Continue*	*Recruit min 1/group*
	c	*3-5 years ago*	*Continue*	*Recruit min 1/group*
	d	*6-10 years ago*	*Continue*	*Recruit min 1/group*
	e	*More than 10 years ago*	*Continue*	*Recruit min 1/group*
9	How do you know how much insulin to give prior to a meal? *Read list aloud*			
	a	Always give a fixed amount of insulin based on physician's guidelines	*Disqualify*	-
	b	Checks blood sugar and calculate amount of insulin based on carbohydrates in meal	*Continue*	-
	c	Using a sliding scale	*Disqualify*	-
	d	Other	*Disqualify*	-
10	Do you, or have you ever, used a diabetes management app called "DIY Loop"?			
	a	Yes	*Disqualify*	-
	b	No	*Continue*	-
CGM				

11	Do you/your child use a continuous glucose monitoring (CGM) system to monitor glucose (such as Dexcom, Eversense, FreeStyle Libre)?			
	a	*Yes*	*Skip to Q12*	*Recruit min 8/group*
	b	*No*	*Continue*	*Recruit min 3/group*
12	How many times per day do you/your child typically check glucose with a fingerstick?			
	a	*4 or more*	*Skip to Q13*	*Recruit min 2/group*
	b	*Less than 4*	*Disqualify*	-
13	How long have you/your child been using a CGM?			
	a	*6 months or less*	*Continue*	*Recruit min 2/group*
	b	*6 months+*	*Continue*	*Recruit min 2/group*
Insulin Pump				
14	How do you (or your child) take insulin? *Select all that apply.*			
	a	*Multiple daily injections*	*Skip to Q17*	*Recruit min 3/group*
	b	*Inhaled insulin*	*Continue only if also a/c/d*	-
	c	*Insulin pump*	*Continue*	*Recruit min 8/group*
	d	*Insulin pump with automated insulin dosing*	*Continue*	-
15	How long have you/your child been using an insulin pump?			
	a	*6 months or less*	*Continue*	*Recruit min 2/group*
	b	*6 months+*	*Continue*	*Recruit min 2/group*
16	What model of insulin pump do you/your child use?			
	a	*Omnipod*	*Continue*	-
	b	*Other, record*	*Continue*	*Recruit min 3/group*
Vision				
17	Do you/your child have any visual impairments that are not corrected by contact/glasses?			
	a	*Yes, record: _____*	*Continue*	-
	b	*No*	*Continue*	-
18	Would your/their vision impairment prevent you/them from using a CGM, insulin pump or mobile app independently?			
	a	*Yes*	*Disqualify*	-
	b	*No*	*Continue*	-
Technology				
19	What kind of mobile device do you/your child currently use?			
	a	*iOS (iPhone or iPod Touch)*	*Continue*	-
	b	*Android*	*Skip to Q21*	Recruit min 3/group

20	What model is your/your child's iOS device? *Record response* _____.			
	a	*iPod Touch 4th gen. or newer*	*Continue*	-
	b	*iPhone 8 or older*	*Continue*	-
	c	*iPhone X or newer*	*Continue*	
	d	*Other*	*Continue*	-
21	Would you/your child feel comfortable using an app to help manage your/their diabetes (*for pediatric patients*: with minimal supervision)?			
	a	*Yes*	*Continue*	-
	b	*No*	*Disqualify*	-
22	Do you currently use a smartwatch? *If yes,* What model?			
	a	Yes, Apple Watch	*Continue*	Recruit min 3/group
	b	Yes, other	*Continue*	-
	c	No	*Continue*	-
23	Can you confirm you will have access to reasonably quiet, private, well-lit indoor space for your whole session?			
	a	Yes	*Continue*	-
	b	No	*Disqualify*	-
24	Please go to "fast.com" using a device connected to the internet connection you plan to you during your session. What is your download speed (numbers in large, black type)? Click "Show more info". What is your upload speed?			
	a	Both download and upload speed are 2 Mbps or higher	*Continue*	-
	b	Either download or upload speed is slower than 2 Mbps	*Disqualify*	-
25	Do you have a computer or mobile device (e.g., tablet or smartphone) with a functioning webcam? *If yes*, what type of device do you have?			
	a	Yes, computer/laptop	*Continue*	-
	b	Yes, tablet	*Continue*	-
	c	Yes, smartphone	*Continue*	
	d	No	*Disqualify*	
26	If you participate in the study, you will receive an email from a study researcher with a link to a remote session. You will need to click the link and join with audio and video. Are you OK with that?			
	a	Yes	*Continue*	-
	b	No	*Disqualify*	-
27	If you participate in the study, you will need to download an app onto your phone so we can show you the product prototype. The app does not collect any data and you can delete the			

	app when you have completed your session. Are you OK with that?			
	a	Yes	*Continue*	-
	b	No	*Disqualify*	-

Invitation

Thanks for answering those questions!

Keep in mind that these are not group sessions or focus groups. Sessions will be one-on-one with you and an interviewer. Remember, in this study, we will only ask you to pretend to use the product and then provide your feedback about it, not actually use it.

You will receive $____ for completing the study and filling out the study documents which may include a W9 form and a consent form describing the study and your participation in it. If you like, after you have received your incentive you would be free to keep it for yourself or donate to an organization of your choosing. Please note that we routinely validate our screening responses so a member of our team may reach out to re-ask certain questions. This usually takes no more than a minute or two so your cooperation is appreciated if a follow up call is requested.

After completing the study, you will either receive payment in the form of an electronic gift card or a business check may be mailed to you within 10 business days of you completing the study. The exact payment method will be determined by the study personnel but in no instance will you receive cash.

[Schedule participant]

We will send you some paperwork to fill out by email, please complete it before your scheduled sessions. You must also have a photo ID accessible during your session, a driver's license is best, and any glasses or contact lenses you may wear.

You may not be able to participate in the study unless you have these items with you.

Appendix B: Informed Consent Form

Consent To Participate in Research

Study Name	
Diabetes App Study	
Research Company	**Questions or Comments?**
Core Human Factors, Inc. 1 Belmont Avenue, Suite 704 Bala Cynwyd, Pennsylvania 19004 United States of America	Please call +1-610-668-2673 and reference this project code: 1078 You will be asked to leave a message including a call-back number.
Study Sponsor	
Tidepool	

Please Note
If this study involves your child but not you, the terms “you” and “your” refer to your child.

If this study involves both you and your child, the terms “you” or “your” refer to you and your child both together and as individuals.

Introduction
You are being asked to participate in a research study. It is important that you read the following explanation of the study procedures. This form describes the purpose, procedures, risks, benefits, and precautions of the study. It also describes your right to withdraw from the study at any time. A researcher is available to review and discuss the study and the information contained in this form with you. You will need to sign this form to be in the study. After you review this consent form, the researcher will ask you if you have any questions and will make sure the form is signed before starting the study. You may request a signed and dated copy to keep. You may show this consent form to family and friends before you sign it. You may want to discuss it with them to help you decide if you want to be part of the study.

Purpose - The purpose of this study is to assess if the intended user(s) can safely and effectively use the study Product.

Procedure - Depending on what you signed up for, your participation will include either:

- A 1 hour individual session, followed by a 2 hour session after a 1 hour break, or
- A 3 hour session, followed by a 2 hour session after a 1 hour break

with a study moderator. The whole study will include a total of approximately 30 participants. This is a simulated use study. You will not be delivering drugs to or using the Product on yourself or others.

You will:

1. Review and sign this consent form
2. Receive an introduction to the study
3. Answer some preliminary questions
4. Receive training related to the study Product
5. Have a waiting period of 1 hour and return the after the break
6. Simulate use of the study Product
7. Answer some follow up questions

You do not need to complete every task or answer every question. You will not be penalized if you skip any tasks or questions.

All of the procedures in this study are experimental and are done for the purposes of this study alone.

Risks - This is a simulated use study. To the best of our knowledge, the things you will be doing have no more risk of harm than you would experience in everyday life. In addition, we will minimize the risk of injury to you in the course of this study.

Potential risk(s)	How we minimize risk(s)
Any information collected will be stored securely. However, there is always a risk that someone who should not have access to this information gets access without permission such as in the rare event of a data breach.	Your name will not be associated with any data collected during the study session. Instead, a unique identifier will be assigned to each participant. The Researcher and the Study Sponsor will take steps to control all information collected during the study, but cannot guarantee that sensitive personal information will never be disclosed.

If at any time you feel uncomfortable or have any questions or concerns, please let the Researcher know. You may inform the Researcher at any time if you no longer want to continue the study session. You can decide not to participate for any reason, without consequences.

Benefits - You will receive no clinical or medical benefits for participating in this study. Since you will be helping to test an upcoming product for a diabetes technology company, you may experience pleasant, positive feelings knowing that you are contributing to the broader diabetes community through your efforts.

Alternatives - Since this is a research study and there are no medical or clinical benefits, your alternative is not to participate in this study.

Compensation - You will be compensated for your time if you complete the study.

You will receive the following amount if you complete the study: **$_____.**

Confidentiality - This study is confidential. This means that only members of the study team and those with a need to know will have access to the information you provide during this study. Information that you provide during this study will be kept strictly confidential. Your name will ***not*** be associated with any data collected during the study session. Instead, a unique identifier will be assigned to each participant. Only the study team will have access to the consent forms. This form is kept separate from data collected during the study session. As part of the data analysis and in any reports or related presentations, your data will be combined with that of other individuals and will be identifiable only by a code (not by your name). Your name will not be associated with any data collected during the study session. The study data may be submitted to the Food and Drug Administration (FDA) and other regulatory bodies, but the data will be anonymized and not include your name or identity.

Your information may also be shared as required by law.

Audio/Video Recording - You will be audio and video-recorded during the study sessions, and this recording will be streamed securely to remote viewers employed by the Study Sponsor. Recording is necessary for the Researchers to be able to collect the information needed to evaluate the study Product.

The recordings will be used for later review and analysis (if necessary) by the Researchers and the Study Sponsor. That is, the recording will serve as supporting documentation to the data recorded during the session. The recordings will be labeled with the date of the session and your participant code. Your full name will not be associated with the recording. The recordings will be digitally stored on a password-protected computer(s) and/or on encrypted cloud-based internet platforms. The videos will be accessible only to the Researchers and the Study Sponsor. The Study Sponsor may also further use the recordings for its internal purposes and may share this information internally with its affiliates. The recordings will be erased if they are no longer needed for any of these purposes. Nevertheless, it is understood that the Study Sponsor is the exclusive owner of the recordings, including any copyrights, and that you will not have any right of ownership or other rights in the recordings or data generated from it.

Termination of Your Participation - If you are unable to meet the study requirements or if the study is cancelled, the Researcher or the Study Sponsor may take you off the research study.

New Findings - If the Researcher or the Study Sponsor learns new information that could affect your willingness to take part in the study, you will be informed.

Adverse Event Reporting - In the event of an Adverse Event during the course of your participation in the study (or if you report an event from your experience), the Study Sponsor may need additional information. *Only* in the case of an Adverse Event, we may ask for information to report to the Study Sponsor for follow-up. Information provided in the context of an Adverse Event report will only be used for that purpose. If information is being collected for an Adverse Event, the Researcher will specifically identify those questions for you. You have the option to make the report anonymously. Your willingness to provide additional information or to

be contacted by the Study Sponsor related to an Adverse Event will impact your ability to continue your participation in the study.

Voluntary Participation - You should only take part in this study because you choose to. There is no penalty for not taking part or leaving the study early. You have the right to stop at any time. Just tell the Researcher that you want to stop.

Volunteer's Statement - I understand that my participation in this research study is voluntary and that I may refuse to participate at any time without penalty.

If I have any questions about my rights as a research participant in this study or in the unlikely event of a research related injury, I may contact the Researcher(s), listed above.

I have read or had the above information explained to me, I have had the opportunity to ask questions about the information, and I understand the information.

I agree to participate in this study and I have been offered a copy of this signed and dated form for my own records.

By signing this form, I have not waived any of my legal rights.

Study Participant (or Legal Guardian, if Study Participant is a minor)

_____	_____	_____
(Print Name)	*(Sign Name)*	*(Date)*

If Study Participant is a minor, print Study Participant's name: _____
(Print Name)

For Administrative Use Only – All Fields Must be Completed Before Enrollment	
_____	Participant's Date of Birth
_____	Calculated Age of Participant on Date of Consent
[ ] Yes	Participant printed, signed, and dated above. – ALWAYS REQUIRED
[ ] Yes [ ] No	Participant *above* legal age of consent. – IF NO, GUARDIAN REQUIRED
_____	**Initials of person who explained this study to the participant and guardian**

Intellectual Property Ownership Agreement

Inventions, Discoveries, and Improvements

I, the undersigned, agree that any input that I provide during the course of this study can be employed by the Study Sponsor for research purposes. I further agree that all inventions, discoveries and improvements, whether patentable or unpatentable, made, devised, or discovered by me during the course of this study will become the property of the Research Company and/or Study Sponsor and will be their sole and exclusive property, and further that I shall not acquire any rights to utilize or distribute any such data my participation in the study has generated.

Study Participant (or Legal Guardian, if Study Participant is a minor)

_____	_____	_____
(Print Name)	*(Sign Name)*	*(Date)*

If Study Participant is a minor, print Study Participant's name: _____
(Print Name)

Appendix C: Informed Assent Form

Assent Form

To be reviewed and signed by anyone under 18 years of age.

WHAT IS THIS ABOUT?

We are doing a research study about a smartphone app that helps people manage their diabetes. A research study is a way to learn more about people and the things that they use. Before you decide if you would like to be in this study, there are some things that you should know. This research will not be good or bad for your health. It is only so that we can learn how you might use the product.

WHAT WILL I BE ASKED TO DO?

If you decide to do this study, you will be asked to:

1. Answer some basic questions about yourself
2. Learn how to use the Product for about 1 hours or 3 hours, depending on what you signed up for
3. Have a break of 1 hour
4. Pretend to use the Product and answer some follow up questions for about 2 hours

You do not have to be in this study if you do not want to be. You can also ask the researcher to stop at any time. That is OK.

CAN ANYTHING BAD HAPPEN TO ME IN THIS STUDY?

This is a simulated study. That means that you will pretend and show us how you would use the product. You will not take any medicine. You will not give anybody any medicine.

If you feel uncomfortable at any point during the study, please tell an adult so that we can try to help. There is a very small chance that someone else may learn your name, your answers, or that you were in this study.

WHAT WILL HAPPEN AFTER I AM IN THE STUDY?

When we are finished with the study, we will write a report about what we learned. The report will not include your name or that you were in the study.

WHO CAN I TALK TO ABOUT THIS STUDY?

The adult with you today knows about the study. You can talk to the adult who is here with you today. You can talk to the adult who signed the consent form and you can talk to the researcher (the person who will be talking to you during the session) at any time. Please talk with them before speaking with anyone else.

DO YOU WANT TO BE IN THE STUDY?

If you would like to be in the study, please fill in the lines below. Remember, you do not have to be in the study if you do not want to.

I, _____, want to be in this research study.
(Print name)

_____ _____
(Sign or mark here) *(Date)*

Appendix D: Moderator's Guide

Throughout the Moderator's Guide text in italics or bold are not said aloud.

Date: _____ Participant ID: _____

General Introduction

Thank you for being here. My name is *[Moderator's name]* _____ and I work at Core Human Factors, an independent research company. Today we are conducting research on a new Product that is intended to manage Type 1 Diabetes. We are interested in collecting your feedback on the Product.

Before we begin, did you have any questions about the informed consent form you signed? [*Confirm informed consent form is completed and answer any questions]*

Please keep in mind that we are not here to evaluate you at all during the session. You are here to help us evaluate this Product. There are no right or wrong responses. We just want to learn about the Product from your perspective. Also, I did not design the Product so you do not need to worry about my feelings when you talk about what you like or dislike about it; we want your honest feedback. Do you have any questions before we begin?

Now I have just a few background questions to confirm. These may sound similar to the questions you already answered on the phone.

Demographics

1. Do you live in the United States?
    a. Yes
    b. No
2. Are you willing to be audio- and video- recorded for this study?
    a. Yes
    b. No
3. Have you been professionally trained or educated as a healthcare professional?
    a. Yes
    b. No
4. What gender do you identify with?
    a. Female
    b. Male
    c. Other
5. What is your age?

   a. Record Response: _____

6. Have you been diagnosed with Type 1 Diabetes?
   a. Yes
   b. No
7. Does your diabetes require the use of insulin therapy?
   a. Yes
   b. No
8. *Adult caregivers only*: How often do you assist your child with counting carbohydrates or dosing insulin?
   a. Most of the time
   b. Some of the time
   c. Rarely
9. How long ago were you diagnosed with T1D?
   a. *Record Response* _____
10. Do you use a CGM?
   a. Yes (Skip to Question 12)
   b. No
11. How many times a day do you typically check your glucose with a fingerstick?
   a. *Record response:* _____
12. How long have you been using a CGM?
   a. *Record response:* _____
13. How do you take your insulin?
   a. Multiple daily injections
   b. Inhaled insulin
   c. Insulin pump
   d. Insulin pump in conjunction with automated insulin dosing
14. How long have you been using an insulin pump?
   a. *Record response:* _____
15. What model of insulin pump do you use?
   a. Omnipod by Insulet
   b. Other, record response: _____
16. Have you used DIY Loop either in the past or currently?
   a. Yes
   b. No
17. Do you have any visual impairments that are not corrected by contacts/glasses?

   a. Yes, *record response:* _____

18. Would your vision impairment prevent you from using a CGM, insulin pump or mobile app independently?
    a. Yes
    b. No
19. What kind of mobile device do you currently use?
    a. Android
    b. iOS
20. What model iOS device do you use?
    a. *Record response:* _____
21. Would you feel comfortable using an app to help manage your diabetes with minimal supervision?
    a. Yes
    b. No
22. Do you currently use a smartwatch?
    a. Yes, *record model:* _____

Technical Equipment Check

Thank you for answering those questions. Now we want to check that all of the video equipment is working.

[Conduct tech check, ensuring webcam and screen share are operational, as necessary]

Training Session

As you know, this study consists of 2 separate sessions. Today we are going to introduce you to the product and show you how to use it. It is an app called Tidepool Loop that is intended to help people with Type 1 Diabetes manage their insulin therapy. When we meet later today, we'll ask you to pretend that you need to use the app for various tasks. Please treat this session as if you will need to use the Product in real life, and this is your opportunity to learn how to use it. The Product that you will use in the study will act just like the actual Product. Keep in mind, that you're not going to actually be administering insulin to yourself or anyone. Instead, all of the information you will see in the app is simulated. Does this make sense? Do you have any questions?

[Pump inexperienced participants only]: This is _____ *(introduce CPT), who is* a certified pump trainer. They are going to provide you information about how to use the Omnipod insulin pump. After that, we will also take a look at the Tidepool Loop app.

[Allow participant to complete CPT training]

[All participants]: Let's imagine your doctor prescribed you Tidepool Loop, and you installed the app on your phone. The first time you opened the app, this is what you saw. *[Show participant initial screen]*. Go ahead and do whatever you would do in real life to continue using this app.

[Allow participant to complete in-app training]

Assessment	Score	Root cause
PPT. Completes in-app Tidepool Loop tutorial and onboarding SC: Completes in-app Tidepool Loop tutorial and onboarding	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	
TCL. Proceed through in-app Tidepool Loop tutorial and onboarding and toggle on Closed Loop On mode SC: Toggle on Closed Loop On mode	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	

Do you have any more questions? Would you feel comfortable using the Tidepool Loop app on your own in real life at this point?

[ ] Yes *[ ] No (Answer any questions with remaining time, otherwise dismiss from study)*

Ok, that is all we have for you this session. As a reminder, our next meeting is scheduled for *[confirm testing session time]*.

Testing Session

Today we are going to be looking at the product you were trained on earlier today, the Tidepool Loop app. The prototype you will be using today looks and acts like the proposed Product. Keep in mind, you're not actually going to be administering insulin to yourself or anyone. Instead, all of the screens you will see in the app are simulated.

Also, I want to remind you that we are not testing you today. You are here to help us evaluate this Product. There are no wrong questions or responses. We just want to learn about the Product from your perspective. Do you have any questions before we continue?

We would like you to imagine that you have been prescribed Tidepool Loop by your doctor to help you manage your diabetes. Let's say they recently recommended a change to your therapy

settings and you need to update the settings in the app. *[Provide participant simulated prescription]*. Please show me how you would do that.

Assessment	Score	Root cause
SWT. Navigate to Therapy Settings management screen Tap Temporary Correction Ranges SC: Navigates to Workout Temp Adjust	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	
EWT. Edit Workout Temp Adjust SC: Edits Workout Temp Adjust per prescription	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	
SWS. Taps Save SC: Taps Save	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	
SCR. Navigates to Therapy Settings management screen Tap Carb Ratio SC: Navigates to Carb Ratio	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	
ECR. Edits Carb Ratio SC: Edits Carb Ratio per prescription	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	
SCS. Taps Save SC: Taps Save	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	

Now I am going to ask you to perform a few tasks using the Tidepool Loop app.

Assessment	Score	Root cause
Let's imagine you were going to eat lunch, and you were planning on having about 25 g of carbs. Please show me what, if anything, you would do in the Tidepool Loop app. ECE. Taps Carb Entry icon SC: Selects Carb Entry icon	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	
ECC. Enters Amount consumed SC: Enters Amount consumed	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	
CBL. Reviews recommended bolus and inputs amount to bolus SC: Manually enters intended amount, or taps the recommended amount	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	
CBA. Confirms bolus SC: Confirms bolus - User can use FaceID, TouchID or passcode.	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	
What would you do if you wanted to stop that bolus? SIB. Taps the Stop icon on temporary status banner while a bolus is in progress SC: Taps "stop" to halt bolus in progress in temporary banner or status bar	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	
Let's say you wanted to edit a carb entry you made earlier. Instead of 25 g of carbs, you had 10 g of carbs. Show me how you would make that edit. RCE. Navigate to Carb Entries screen SC: Taps on active carbohydrates graph to navigate to Carb Entries Screen	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	

ECE. Edit Amount of Carbs SC: Edit Amount of Carbs	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	
TSC. Taps save SC: Taps save	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	
What, if anything, would you do with the Tidepool Loop app if you were planning on working out soon? TWA. Toggle on Workout Temp Adjust SC: Toggle on Workout Temp Adjust	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	
Where would you check to see if the workout temporary adjust was enabled? KWA. User comprehends if Workout Temp Adjust is enabled. SC: Identifies where on the Home Screen (Correction range or toolbar button state) they would look to see that the mode was enabled	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	
Let's say you wanted to enter a manual glucose reading of 215 mg/dL and deliver a correction bolus. Can you show me how you would do that? SMG. Navigates to blood glucose entry on bolus screen SC: Taps on prompt to enter blood glucose reading	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	
EBG. Enter BG value and taps continue. SC: Enters BG value as intended and taps "Continue"	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	

SBL. Inputs amount to bolus SC: Manually enters recommended bolus amount, or taps the recommended amount	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	
CBO. Confirms bolus SC: Confirms bolus - User can use FaceID, TouchID or passcode.	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	
Now let's say you wanted to suspend all insulin delivery. Show me how you would do that. SSI. Tap Suspend Insulin SC: Taps Suspend Insulin and Confirms suspension of insulin	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	
Ok, and now imagine you are ready to resume insulin delivery RSI. Tap Resume Insulin on the temporary banner on the Home Screen or Navigate to Pump Status/Settings screen and Tap Resume Insulin SC: Taps "Resume Insulin" on the temporary banner on the Home Screen or navigates to Pump Status/Settings screen and taps "Resume Insulin"	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	

Thanks for doing all of that. Now I'm going to show you a few screens and ask you some questions about them.

Assessment	Score	Root cause
***[Present user with home screen]* Based on this screen, what is your current glucose reading?** ISG. Understand current sensor glucose SC: Identifies current sensor glucose reading	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	

[Present user with screen shot] **Based on this screen, where would you look to find your glucose prediction?** IPG. Understand glucose prediction SC: Correctly points to or identifies glucose chart and points to glucose prediction dashed line	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	
[Present user with screen that shows hypoglycemia within the next 30 minutes] **Based on this screen, what can you tell me about how your glucose is predicted to change?** IPH. Comprehend glucose prediction SC: Correctly identifies a predicted hypoglycemia when the glucose chart shows a hypoglycemic episode within the next thirty minutes	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	
[Present user with home screen] **Where would you look to check the status of Tidepool Loop (e.g., Closed Loop On vs. Closed Loop Off mode)?** SID. Views Tidepool Loop status indicator SC: Identifies Tidepool Loop status indicator	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	
[Present participant with screen with "Closed Loop Off" Status] **Based on this screen, what is the status of Tidepool Loop?** ***Follow-up:*** **If you wanted Tidepool Loop to continue automating insulin delivery, what should you do?** OFF. User detects/comprehends automation of insulin delivery currently happening SC: Identifies automation of automated insulin delivery is not happening and indicates need to troubleshoot.	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	
[Present user with home screen with Tidepool Loop indicator icon and CGM status icons displaying a current error] **Based on this screen, what if anything would you do if you wanted Tidepool Loop to continue automating insulin delivery?** VCE. Views current error SC: Identifies how to check the glucose chart and taps the	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	

CGM status icon for more information about the recency of the glucose data and error state.		
[Present participant with "Loop Failure" alert] **What, if anything, would you do if you saw this?** ***Follow up*****: What information is this trying to convey?** RAL: Respond to alert or alarm *SC: Comprehends Tidepool Loop is not automating insulin delivery and dismisses notification. Comprehends need to troubleshoot connectivity.*		

Apple Watch Tasks

[For Apple Watch experienced participants only]: Now I'd like you to show me how you would perform some tasks in Tidepool using the Apple Watch interface.

Assessment	Score	Root cause
Let's say you were planning on having a snack. You want to have 20 g of carbs. Can you show me how you would make a carb entry using the Apple Watch? WCA. Enter Amount Consumed SC: Inputs/selects by rotating Digital Crown/pressing + or - carb amount	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	
WWB. Review Bolus Recommendation and Taps Save & Bolus SC: Taps Save & Bolus	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	
WCB. Confirms bolus SC: Confirms and delivers bolus entry by rotating Digital Crown	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	
Let's say you were planning on working out soon. Can you show me how you would turn on workout temp adjust mode using the smartwatch? WWT. Toggle on Workout Temp Adjust	[ ] S [ ] UE [ ] CC [ ] UD [ ] A	

SC: Toggles on Workout Temp Adjust	[ ] NA	

Knowledge Tasks

Thank you for doing that. Now I have some questions for you. This is not a test of your memory, so feel free to do whatever you would do in real life to answer these questions.

Assessment	Score	Root cause
What, if anything, should you do if the Tidepool Loop app glucose prediction displays a hypoglycemic episode in 30 minutes? RPH. Comprehend predicted glucose SC: Indicates that they should monitor closely and be prepared to treat with fast-acting carbs and optionally to confirm sensor glucose with a fingerstick.	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	
What, if anything, should you do to keep using Tidepool Loop after your phone restarts? LAR. Launches the app after user restarts their phone SC: Knows to launch app again after a phone restart	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	
Imagine you are experiencing high glucose that you would normally treat by administering insulin. What, if anything, should you do differently because you are using Tidepool Loop? DCH. Knows not to change treatment behaviors due to use of Tidepool Loop except to account for any adjustments already made by Tidepool Loop SC: Knows not to change treatment behaviors due to use of Tidepool Loop except to account for any adjustments already made by Tidepool Loop	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	
Imagine you are experiencing low glucose that you would normally treat by eating carbs. What, if anything, should you do differently because you are using TIdepool Loop? DCL. Does not change existing behaviors to treat low glucose	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	

SC: Knows not to change treatment behaviors due to use of Tidepool Loop		
Imagine you are experiencing frequent, recurring hypoglycemic episodes. What, if anything, should you do? **HCP**. Contact HCP SC: Knows to contact HCP and/or adjust settings with HCP	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	
[Smartwatch experienced participants only]: **Where does your phone need to be in order to use the Tidepool Loop app through your Apple Watch?** WPP. Knows when to use Tidepool Loop on an Apple Watch. SC: Comprehends that watch can not be used with Tidepool Loop without proximity to phone	[ ] S [ ] UE [ ] CC [ ] UD [ ] A [ ] NA	

Follow-up on Use Errors, Close Calls and Operational Difficulties

How was your overall experience using this app today?

Now I would like to talk more about your experience using this Product? Tell me, did you have any difficulties today? *[Record in appropriate columns assessments of root causes for items above.]* Now I would like to revisit some things that I observed. The purpose of this is to understand what you were thinking and seeing as you used the Product. Remember, you can't do anything wrong, we just want to see what it will be like when people use the Product in real life.

[Note: Walk through each use error, close call, and operational difficulty and probe on why it happened. Record in appropriate columns assessments of root causes for items above.]

Subjective Feedback Questions

Now I am going to ask you for some additional feedback. *[Based on responses below, probe for any additional root causes as necessary]*.

1. Overall, did you have any additional difficulties using this Product that we have not talked about yet?

2. Is there anything concerning the app or its instructions that you found confusing, misleading, or incomplete?

3. Do you think we learned today what using the product would be like for you in real-life? *[If "no", follow up with:]* How do you imagine this might have gone differently for you in real life? *[Follow up with anything pertaining to critical risks]*

4. Did you have all the information you needed to get started with Tidepool Loop in the in-app onboarding?

5. What additional questions do you have about Tidepool Loop now that you have gone through the training process?

6. What impact do you think Tidepool Loop would have on your life? *[if participant is person with diabetes]*

7. What impact do you think Tidepool Loop would have on your life as a caregiver? *[if participant is caregiver of person with diabetes]*

8. How does Tidepool Loop compare to your current therapy?

9. What is the most useful thing about Tidepool Loop?

10. If you had to summarize Tidepool Loop in one word, what would it be?

Now I am going to ask you for some additional feedback on the Tidepool Loop user interface.

11. What are your thoughts on the Tidepool Loop home screen?

12. How did delivering a bolus with Tidepool Loop compare to other insulin pump systems you've used?

13. What did you think about the process of entering carbs with Tidepool Loop?

14. What do you think about the ability to specify the type of food you are eating?

15. What do you think about the ability to edit a carb entry - e.g., you didn't eat as much as you thought you would?

16. What do you think about the ability to set temporary correction ranges?

17. (Optional) What do you think about the Watch interface?

18. Do you have any additional comments or questions for us about anything?

Appendix E: Simulated Prescriptions

Pediatric	
Carb Ratio	15 g/U
Workout Temp Adjust	140-150 mg/dL

Adult	
Carb Ratio	12 g/U
Workout Temp Adjust	140 -150 mg/dL