US ONYX 2.0 Study: A Clinical Study of the Onyx 2.0 System for Blood Glucose Monitoring in Patients with Diabetes

I have read this protocol and agree to conduct the study as outlined. I also agree that prior to seeking approval from an Institutional Review Board (IRB), the Ascensia Diabetes Care study manager must approve any changes to the protocol

Study Site 06

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Abbreviations

AE	Adverse Event
App	A downloadable application for use on a "smart device". In this study – Contour® Diabetes App 2.0
BG	Blood Glucose
BGMS	Blood Glucose Monitoring System
BLE	Bluetooth Low Energy
CRF	Case Report Form
CV	Curriculum Vitae
DC	Diabetes Care
DMS	Diabetes Management Software
EC	Ethics Committee
EDC	Electronic Data Collection
HCP	Health Care Provider (also called clinician)
IC	Informed Consent
IDE	Investigational Device Exemption
IRB	Institutional Review Board
MDI	Multiple Daily Injections
PI	Principal Investigator
QRG	Quick Reference Guide
RF	Radiofrequency
SAE	Serious Adverse Event
SMBG	Self-Monitoring of Blood Glucose
SSD	Structured Source Documents
UG	User Guide
USB	Universal Serial Bus

1.0 BACKGROUND/INTRODUCTION

Self-monitoring of blood glucose (SMBG) is an important technique for assessing glycemic control in people with diabetes and can be useful for guiding therapy as it allows people with diabetes to evaluate their individual response to treatment. Emerging technologies, such as mobile apps, are helping people to manage their diabetes by providing personalized, real-time, data-driven support. Currently, there are many apps available to directly assist with diabetes management, plus others that help track additional relevant information such as exercise, stress, diet, and medications. Many available diabetes apps involve manual logging of blood glucose and insulin data, which may be inconvenient for users and prone to errors. It is important that results obtained from SMBG are accurate because they are used to make critical decisions about diabetes management, and inaccurate results could lead to nutritional and drug dosing errors.

Until recently, automatic wireless transmission of blood glucose data using smartphone technology was not available to people with diabetes. A new blood glucose monitoring system (BGMS), the Contour® Next ONE has been developed (development name ONYX) for use with currently available Contour® Next test strips. The new BGMS features a wireless-enabled, blood glucose meter that links to a smart mobile device via Bluetooth® connectivity. The system is designed to sync with the Contour Diabetes App that was developed for Android or iOS operating systems and can be used on a smartphone or tablet. The app provides multiple functions intended for a simple-yet-comprehensive user experience.

Contour Diabetes App 1.0

The initial release of the App provides users with features that allow them and their health care provider (HCP) to assess their diabetes control with features such as sequential day views, modal day views, glucose pattern detection with notifications, and smart test plans. The Contour Diabetes App retrieves BG readings from the meter, and allows users to view the readings and edit their attributes (meal marking, notes, etc.) as well as edit their meter settings. It combines readings with contextual data like food and medication to educate and motivate people with diabetes to take action to improve the state of their disease.

Contour Diabetes App 1.0 includes notifications of “Critical High” and “Critical Low” blood glucose patterns if recognized in the patient data. Smart test plans (also called Smart Reminders) can help the user manage personal diabetes care regimens by providing pre-set test and appointment reminders. Basic testing plans are included in App 1.0. The App includes a Cloud Services Platform which offers online remote storage of user data and account information. User data is synchronized with the Cloud and with other customer owned devices.

Contour Diabetes App 1.0 was tested in the hands of people with diabetes in a study conducted at one clinical site in the US[1]. This study enrolled 45 persons with diabetes (type 1 or type 2 diabetes on insulin therapy) who used the Contour Next One meter and Contour Diabetes App as part of their routine diabetes management at home for 3 weeks. At the end of the study, subjects completed a questionnaire about their experiences using the system. In summary 95% of subjects reported they were able to successfully sync their blood results on the meter with the App, as well as access and interpret the blood glucose displays in the App.

[1] Bailey T, Davis T, Wallace J, Pardo S, Morin R, *Usability of a New Blood Glucose Monitoring System (BGMS) With A Mobile App,* poster presented at the 76th Annual American Association of Diabetes Meeting, June 12, 2016, New Orleans, LA

In addition, the accuracy of the Contour Next One system was demonstrated in laboratory and clinical settings. In a clinical user evaluation study, with 329 patients with diabetes, 99.4% of the Contour Next One results were within ±15mg/dL/15% of the laboratory reference results.[2] These results met the International Standard ISO 15197:2013(E).

The Contour Next One BGMS with Contour Diabetes App 1.0 has received CE mark and has been commercially launched in Europe. Note that this study will test the next release version of the Contour Diabetes App 2.0.

Contour Diabetes App 2.0

The Contour Diabetes App 2.0 is an updated version of the CE marked Contour Diabetes App 1.0.

This feature set includes sequential day views (My Readings view), modal day view (Expanded Graph view), glucose pattern detection with notifications, and smart test plans. The glucose pattern notifications provide messages to the user that are informational, not prescriptive, using the paradigm "Information, Motivation, and Behavior (IMB)". These messages are based on algorithmic recognition of patterns in the users' glucose results and are intended to help guide the user through a series of educational screens to identify the data which triggered the pattern and explore options for addressing the situation. Smart test plans (also called Smart Reminders) can help remind the user to perform certain tasks to improve the quality of information gathered in relationship to a specific event or circumstance (i.e. preparing for a visit with a healthcare professional or if an individual does not like to test).

In summary, Contour Diabetes App 2.0 which is the investigational mobile application under test in this study contains the following updates to App 1.0:

- Detects an additional 19 patterns to the original two (Critical High and Critical Low)
- Expanded smart testing reminder plans

To optimize the functionality of the system, it is imperative that persons with diabetes provide feedback regarding the effectiveness of the Contour Next One system in routine diabetes management, with a focus on the new features in Contour Diabetes App 2.0. This protocol describes a clinical study where people with diabetes will evaluate the Contour Next One blood glucose monitoring system in conjunction with an investigational Contour Diabetes App 2.0.

2.0 OBJECTIVES

Primary Objective:

The purpose of this study is to assess the utility of the Contour Diabetes App 2.0 when used with the Contour Next One meter (the Onyx system) in the hands of subjects with type 1 diabetes or insulin-using subjects with type 2 diabetes. It is designed to determine the subjects' self-reported success in utilizing the features of the system. Each feature will be evaluated independently, by including a series of statements about each feature set for which a numerical score or rating will be provided by subjects. The evaluation includes:

- Obtain a synced blood glucose reading

[2] Christiansen M, Greene C, Pardo S, Warchal-Windham ME, Harrison B, Morin R, Bailey T, *Accuracy and User Performance Evaluation of a New Blood Glucose Monitoring System in Development For Use With CONTOUR Next Test Strips,* Poster presented at the 15th Annual Diabetes Technology Meeting (DTS), Oct 22, 2015, Bethesda, MD

- Recognize and use "Smart Reminders"
- Access and interpret glucose displays such as Expanded Graph and My Readings views
- Recognize glucose pattern notifications (as applicable since all subjects may not receive pattern messages)

Goal: For the following features, at least eighty five percent (85%) of potential users should be able to report that they were able to successfully utilize the feature. A rating of 1, 2, or 3 for each feature (1=strongly agree, 2=agree, 3=neither agree nor disagree, 4=disagree, 5=strongly disagree) indicates that the subject was able to successfully utilize the feature. These include:

- Obtain a synced blood glucose reading
- Recognize and use "Smart Reminders"
- Access and interpret glucose displays such as Expanded Graph and My Readings views.

Other Objectives:

1. Ease of Use: Determine ease of use of the Contour Diabetes App 2.0 when used with the Contour Next One meter via subjects' self-assessment.
2. Hypoglycemia Frequency: Report severe hypoglycemia events
3. Glycemic Control: Measure changes in hemoglobin A1C and fructosamine levels
4. Total daily insulin dose: Evaluate changes in self-reported insulin doses throughout the study. Both bolus and basal insulin doses are reported and, if insulin varies from day to day, average units will be reported.
5. Clarity of User Instructions: Obtain the subjects' ratings on the clarity and utility of the instructions.
6. Subject Feedback: Obtain the subjects' opinions about their experiences using the Contour Diabetes App 2.0 in conjunction with the Contour Next One meter system.
7. Overall experience with the system Hardware/Software: Obtain data on hardware/software failures and unexpected events using the App.
8. Weight/BMI: Measure changes in weight and BMI
9. Feature Utilization rates (from cloud data)

3.0 STUDY DESIGN

This study will test the investigational Contour Diabetes App 2.0 with the investigational Contour Next One system in the hands of users managing their diabetes at home. The study conducted under this protocol will be conducted at one site in the US. The study will follow federal regulations (US) for conducting a study using investigational devices in routine diabetes management. Approximately 48 subjects with diabetes will come to the study sites and receive the investigational Contour Next One meter, the Contour Diabetes App 2.0 and the following commercially available products: Contour Next test strips, Contour Next control solution, lancing devices and lancets.

Subjects will be assisted in loading the Contour Diabetes App 2.0 onto their personal mobile device after enrollment. They will then use the BGMS system in conjunction with the downloaded App to manage their diabetes at home for six weeks – two weeks run-in to initiate the pattern manager, and four weeks in-life. They will be notified that certain aspects of the app will not take effect until a full two weeks of glucose data has been entered. They will return to the clinic after approximately six weeks and complete a questionnaire regarding the usability of the devices and their experience with the devices in their daily diabetes management routine. (See Appendix C Schedule of Events for details). Forty (40) subjects must complete the study.

Office Visit 1 – Study enrollment, including demographics and diabetes history information. Receive meter, strips, and instructions, and download the App: Approximately one hour. Blood drawn for HbA1c and fructosamine, weight and height measured, total (may be an average if insulin varies) daily insulin dose recorded.

Follow-up phone calls to subjects: At least 2 scheduled phone calls to each subject during the study – the first at approximately week two, the second at approximately week four. Subjects will be reminded to NOT update their mobile devices to Android 7 versions.

Office Visit 2 – approximately six weeks later: 1 hour to complete questionnaires and be interviewed by staff. Blood to be drawn for HbA1c and fructosamine, weight measured, total (may be an average if insulin varies) daily insulin dose reported.

Safety and Efficacy Endpoints:

Primary Endpoints

Questionnaire outcome – Subjects will complete a questionnaire at the end of the study at Visit 2 that will assess the usability of the App 2.0 with the meter and their experience using the Contour Diabetes App 2.0 system in their daily diabetes management routine. The App features will be evaluated independently by asking a series of questions about each. The features evaluated may include:

- Obtain a synced blood glucose reading
- Recognize and use "Smart Reminders"
- Access and interpret glucose displays such as Expanded Graph and My Readings views.
- Recognize glucose pattern notifications (as applicable since all subjects may not receive pattern messages)

Goal: For the following features, at least eighty five percent (85%) of potential users should be able to report that they were able to successfully utilize the feature. A rating of 1, 2, or 3 for each feature (1=strongly agree, 2=agree, 3=neither agree nor disagree, 4=disagree, 5=strongly disagree) indicates that the subject was able to successfully utilize the feature. These include:

- Obtain a synced blood glucose reading
- Recognize and use "Smart Reminders"
- Access and interpret glucose displays such as Expanded Graph and My Readings views.

Statements such as 1, 8, 9, and 42 in Appendix A correspond to statements subject to the 85% criterion. These statements are shaded.

Secondary Endpoints

- A change from baseline to completion of:
    - HbA1c
    - Fructosamine
    - Weight
    - BMI
    - Total Daily Insulin (self-reported bolus and basal doses)
- Feature Utilization rates

Safety

The following are to be captured:

- Adverse events
- Severe Hypoglycemic episodes
- Hospitalizations

4.0 SUBJECT INCLUSION AND EXCLUSION

Approximately forty eight (48) subjects with diabetes will be enrolled.

Inclusion Criteria

The subject must:

- Be aged 18-75 years, male or female
- Read and understand English
- Have diagnosis of type 1 (goal is 40% to 70%) or insulin-using type 2 diabetes for at least 6 months
- Be taking multiple daily insulin injections (MDI) of at least two pre-meal bolus insulin injections daily or using an insulin pump (Goal is not more than 30% of subjects using insulin pump therapy)
- Performing self-monitoring of blood glucose at home at least twice daily
- Have an iOS mobile device or Android mobile device with Bluetooth capability
  - iOS device: iPod, iPad, or iPhone 5 or later version with iOS 9.x or 10.x software
  - Android: smart phone, software version 5.x or 6.x.
  - Bluetooth: software version 4.0 or higher
- Agree NOT to update the software on their mobile device until after the study is concluded, as follows:
  - No updates of Android device to upcoming Android version 7 (Nougat)
- Be willing to utilize the Contour Next One meter and the Contour Diabetes App 2.0 on personal mobile device which communicates to meter to manage diabetes and be willing to keep a study diary

Exclusion Criteria

- Known Hemophilia or any other bleeding disorder
- Pregnancy (reported by subject; no pregnancy test required)
- Current user of Contour Next One BGMS including Contour Diabetes App.
- Physical, visual or neurological impairments that would make the person unable to perform testing with the Contour Next One BGMS or to use the Contour Diabetes App
- Working for a competitive medical device company, or having an immediate family member or someone who is not a family member but is living within the household of someone who works for such a company.
  - Immediate family members are the subject's parents, spouse, children, and siblings, including the parent's spouse; step children and adopted children and their spouses.

- A competitive medical device company is a company that provides a medical device or components of a device that is related to diabetes. For example, people who are not eligible are those who work for companies that create or manufacture the following (or a company that is in a partnership with a company that provides such devices): lancing devices, blood glucose monitoring systems, continuous glucose monitoring systems, insulin pens, or systems related to the measurement of HbA1c. People who are eligible are those who work for companies associated with products such as wound dressings, medications or dietary products.

- A condition, which in the opinion of the investigator or designee, would put the person or study conduct at risk (reason for exclusion will be clearly documented by investigator or designee on the subject disposition form).

5.0 MATERIALS AND METHODS

5.1 Study Details

5.1.1 General

a) This study will evaluate the Contour Diabetes App 2.0 system at one site where study staff have been trained on the Contour Diabetes App and Contour Next One system.

b) At least forty (40) subjects must complete the study

c) All subjects will complete the informed consent (IC) process.

d) Inclusion/exclusion information will be collected. Subjects must meet these criteria to be enrolled in the study.

e) A unique study number will be assigned to each subject.

f) The study staff will document subject demographics (including both screen failed and enrolled subjects), diabetes history and management. Subject's responses to demographic and medical history questions will be self-reported. Medical record verification is not required.

g) Original study data reported at the clinic will be collected on paper structured source documents (SSDs). Study staff will complete all SSDs. Laboratory reports for A1C and fructosamine will serve as their own source docs. Electronic data collection (EDC) will be used for permanent data storage and will be entered by site staff.

h) The subject will be informed that, if during the course of participating in this trial, he/she would need to perform a personal diabetes management procedure, verification of blood glucose measurements should be performed with the user's typical pre-study procedures.

5.1.2 Visit 1: BGM Training and Testing

a) The subject will be provided with a Contour Next ONE meter, Contour Next test strips, Contour Next control solution, Contour Next ONE User Guide (UG) and Quick Reference Guide (QRG) and Study Diary. In addition, each subject will be provided a lancing device system and lancets.

b) The lancing system, any remaining Contour Next strips and control solution may be kept by the subject after the study. The meter, QRG and UG must be returned after the study is completed.

c) For orientation/instruction, the subject will be directed to read specific sections of the instructional materials. The study staff will then review these materials with the subject and provide an overview of the system.

d) The subject will perform a control test with their study meter to assure the meter is working properly.

e) The subject will perform a fingertip blood test with the Contour Next One system and following the App download, verify in the presence of the study staff that the reading is syncing with the App.

5.1.3 Visit 1: Contour Diabetes App 2.0 Setup

a) In the presence of the subject, a de-identified email account will be created by the study staff for each subject. Ascensia Diabetes Care will provide the format of these email account names and the study staff will direct this setup. An example of the email address format is: ADC6001@xxxxx.com where 6001 is the subject ID.

b) The App will be downloaded onto the subjects' personal phone with the assistance of the study staff, and Ascensia Diabetes Care technical support staff, as needed.

c) The initial setup of the App will be overseen with the assistance of the study staff. All steps in the Profile setup must be entered. Personal identifiable information will **not** be entered into the App.

d) The subject will be trained on the use of the App using the instructional materials provided. The study staff will answer questions to ensure they know how to perform a blood glucose test, review results, enter attributes such as meal marking, notes, medications, exercise, etc.

e) The staff will verify along with the subject that the App is properly loaded onto the personal mobile device, the meter is successfully paired to the App and the meter reading is properly synched to the App.

f) The users will be informed that some pattern notifications will be enabled only after two weeks of glucose data have been entered.

g) After initial setup the study staff will inform Ascensia Diabetes Care of the subject's enrollment, the subject's de-identified email address and user ID. The Ascensia Diabetes Care administrator will verify that the profile was correctly set up via the Cloud.

5.1.4 Home study

a) Subjects will be expected to use the App at home for six weeks for their routine diabetes management. They will be expected to:
- Synch the meter readings with the App
- Recognize glucose pattern notifications (as applicable since all subjects may not receive pattern messages)
- Recognize and use "Smart Reminders"
- Access and interpret glucose displays such as expanded graph (modal day) and My Readings (sequential logbook).

b) Throughout the study at home, subjects can use the Study Diary to record

- Any notations about the use of the system
- Confusing features or problems they encountered
- Other feedback they would like to recall for the final visit questionnaire and comments.

The diary should be brought to the final study visit and will be reviewed by the study staff. It can be used by the subjects to refresh their memories during the questionnaire phase. This diary will be a source document, to be placed in the study file but not entered into the Electronic Data Capture system (EDC).

c) Ascensia Diabetes Care technical support staff will be available for providing technical support as needed throughout the study via telephone.

5.1.5 Scheduled Telephone Contacts

a) At approximately 2 and 4 weeks after each subject's Visit 1, the site staff will contact the subject (e.g., via telephone) for an update on their experience with the Contour Next One system including the following:
   - Safety update including any severe hypoglycemic events or hospitalizations which are both considered Adverse events
   - Total Daily Insulin (basal and bolus insulin)
   - User feedback about the usability of the system including unexpected, confusing events or problems with the system
   - Friendly reminder not to upgrade the software on their mobile device (to Android 7 versions) until after the study is concluded.

5.1.6 Site Visit 2

a) Each subject will return to the clinic after approximately six weeks, bringing with them the meter, UG, QRG, mobile device and study diary.
b) Subjects will complete a questionnaire regarding the utility of the device and their experience with the device in their daily diabetes management routine, and get a blood draw for the final A1C and fructosamine test. See Appendix C for schedule of procedures.
c) During the questionnaire phase, subjects will be provided with printed screen shots of the App which identify App features mentioned in the questionnaire.
d) Staff will interview the subject for an update on their experience with the Contour Diabetes App 2.0 when used with the Contour Next One meter including the following:
   - Safety update including any severe hypoglycemic events or hospitalizations which are both considered Adverse events
   - Total Daily Insulin (bolus and basal)
   - User feedback about their experience using the system including unexpected, confusing events or any problems they encountered.

5.1.7 Post Study

a) After the subject has completed the study, the de-identified App data which has been sent to the cloud will be retrieved by the Ascensia Diabetes Care system administrator.
b) After all data is successfully retrieved from the cloud, the subject's App will be de-activated and the subjects' study email accounts will be deleted.

c) All used study meters will be cleaned and disinfected following the instructions in the User Guide. All study meters will be returned to Ascensia Diabetes Care.

5.2 Staff Training for Subject Visits

The site study staff will participate in a training session conducted by the Ascensia Diabetes Care Study Manager or designee. A Smart device (both Android and iOS) will be provided by Ascensia Diabetes Care to demonstrate the App to the study staff. Ascensia Diabetes Care study manager (or designee), study monitor, and Ascensia Diabetes Care technical support staff may all be present for the training.

5.3 Resources Supplied by Ascensia Diabetes Care

Staffing

- Ascensia Diabetes Care Study Manager
- Study Monitor
- Ascensia Diabetes Care technical support personnel as needed

Materials

- Protocol
- Structured source documents, worksheets and study diary
- Electronic data capture system
- Draft of Informed Consent document
- Contour Next One meters
- Contour Next test strips (300 strips for each subject)
- Contour Next control solution
- Lancing device system and lancets (300 lancets for each subject)
- Access to Contour Diabetes App 2.0 for download
- App instructional materials
- Contour Next One UGs and QRGs
- Subject Study Diary
- Android smart device for training purposes
- iOS smart device for training purposes

5.4 Resources Supplied by the Clinical Site

Staffing

- Principal Investigator and Sub-Investigators, as needed

- Study Coordinator
- Study staff members as needed including phlebotomist
- A data entry person for EDC data entry (Requires Medidata RAVE training)

Other

- Final informed consent documents, and other necessary supporting documents, as appropriate
- IRB submission of protocol and informed consent documents, and other necessary supporting documents, as appropriate
- Computer with internet connection for site access to EDC system
- Wireless internet access
- Facility with adequate space for conducting all testing.
- Approximately 48 subjects who meet enrollment criteria
- Appropriate care/supplies for treating hypoglycemic events if necessary (e.g. nutritional supplements or fast acting glucose tablets/gel)
- Venipuncture supplies
- Measurement of hemoglobin A1c and fructosamine (or send the blood to Central laboratory for these tests)

5.5 Subject Compensation

Subjects will receive nominal compensation for their time and inconvenience as specified in the informed consent form.

6.0 RISK/ BENEFIT ASSESSMENT

Risks Associated with the App

Risks associated with the use of diabetes Apps, which may include some confusion with interpreting the messages shown on the App and inappropriate use of information, could lead to improper management of diabetes.

The App used in this clinical study will not provide any prescriptive advice for diabetes therapy which could be a cause for error in diabetes management. Patients are instructed how to use the information provided by the App appropriate for their diabetes management.

The Contour Diabetes App 2.0 used in this study is an investigational device. But the forerunning Contour Diabetes App 1.0 is CE-marked and has been launched commercially outside the US. The risk management analysis of the Contour Diabetes App 2.0 focuses on any risks related to the additional recognized glucose patterns and smart testing plans implemented in the updated version. While conflicting patterns may be displayed to the user possibly causing confusion in interpretation of the messages, an extensive pattern management algorithm has been incorporated in the system to mitigate this risk and decrease any confusion. Furthermore, the additional smart testing plans included in this update do not add any risks to the device.

Other Known Risks with BGM Use

Risks associated with this study include those associated with obtaining blood from finger and venipuncture.

The following risks are anticipated and will not be reported as Adverse Events (see section 7.0 for further details):

1) Bleeding: Mild bleeding similar to being stuck with a pin
2) Swelling (Edema): A mild swelling similar to a mosquito bite
3) Bruising: Less than one inch across (fingerstick) or 2 inches across (venipuncture)
4) Redness (Erythema): Mild reddening or darkening of the skin in the immediate area around the puncture site
5) Soreness: Mild discomfort at the puncture site resolving (going away) within one to two days (fingerstick) or within hours (venipuncture)

The following risks are unlikely but possible and will be reported as anticipated Adverse Events:

1) Bleeding: Continued bleeding requiring changing a bandage
2) Bruising: A worsening bruise that is firm to the touch
3) Redness (Erythema): Bright redness or skin darkening spreading across the area (fingerstick) or across the arm (venipuncture)
4) Soreness: Worsening pain and/or pain that interferes with activity
5) Infection: Bright redness or skin darkening spreading across the area with warmness and/or swelling, and/or red streaking
6) Nerve injury: Numbness or shooting pain in the forearm
7) Fainting: Dizziness including in extreme cases fainting
8) Numbness in the area of the puncture wound
9) Subjects should be instructed to report such events to the investigator or designee.

Expected Benefits

This study allows persons with diabetes the opportunity to participate in a study designed to evaluate a new product for use in their home diabetes management. But subjects have no further personal individual benefit from study participation regarding their diabetes therapy. Subjects have the opportunity to gain experience with an app-based diabetes data management under the supervision of an investigator.

Risk-Benefit Evaluation

In this clinical study, subjects will not be administered additional drugs and individual diabetes treatment will not be changed due to the study procedures.

Potential risks for the subjects caused by the use of the investigational Contour Diabetes App 2.0 have been evaluated in a systematic risk assessment procedure. The identified risks (“anticipated adverse events”) were classified to be in the non-critical range and do not exceed the risks described in this chapter.

The risks and burden associated with the participation in this clinical study do not exceed the risk and burden associated with the subjects’ regular diabetes treatment. The subjects have no personal benefit from participating in the study, but will be paid compensation.

The insights obtained in this study will help to understand patients' experiences and needs using app-based diabetes management systems which might eventually help patients with diabetes mellitus to better accomplish their treatment goals.

This study allows persons with diabetes the opportunity to participate in a study designed to evaluate a new product for use in his/her home diabetes management program.

7.0 REPORTING OF ADVERSE EVENTS

The procedures to be conducted under this protocol are considered low risk.

7.1 Description and Classification

7.1.1. An adverse event (AE) during a clinical evaluation is "any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device." It is not dependent on whether the event is considered to be related to the investigational product or the study. An adverse event includes events not seen at the beginning of the study, or worsened if present at the beginning. Adverse events can be classified as presented in Table 1.

7.1.2. The next classification to consider is whether or not the AE is Anticipated or Unanticipated. In order for an AE to be considered 'anticipated' it must be listed in the protocol and ICF prior to any occurrence.

7.1.3. For studies on products that have not yet been cleared for market, it is important that all AE's be documented and included in the study file.

7.1.4. An unanticipated serious adverse device effect (USADE) is: Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with a device, if that effect, problem or death was not previously identified in nature, severity or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety or welfare of subjects [MEDDEV 2.7.3].

7.2 Hypoglycemia is defined as having a measured fingerstick (SMBG) or venous glucose result of ≤ 80 mg/dL [3.9 mmol/L] and can be a common occurrence with persons who have diabetes. Hypoglycemic events categorized as severe hypoglycemia will be reported in this trial and will be considered adverse events. Severe hypoglycemia has occurred if the answer is yes to any of the following 3 questions:

1. Did the patient have an episode of suspected hypoglycemia treated with any form of carbohydrate or with glucagon that required the assistance of others to treat?

Note "patient requires the assistance of others to treat" means that neurologic impairment was severe enough to prevent self-treatment in the opinion of those providing assistance to treat.

Assisting a patient out of kindness, when assistance is not required should not be considered as "requiring the assistance of other to treat."

OR

2. Did the patient lose consciousness during the episode?

OR

3. Did the patient have a seizure during the episode?

If the subject experiences a severe hypoglycemic event it will be considered to be an anticipated AE and will be recorded on the Adverse Event Form by the study staff.

7.3 Procedure for Reporting an Adverse Event

7.3.1 All adverse events will be documented during this study by completing the Adverse Event Form. The nature of each event and date of onset, outcome, course, maximum intensity and action taken with respect to treatment should be established. Details of any corrective treatment should be recorded on the AE Form. Investigators should follow-up on the status of subjects experiencing an ongoing adverse event until the event has been resolved, or until the condition has stabilized.

Table 1: Classification of Adverse Event

Serious*	Non-Serious
An adverse event that leads to: a) death; b) a serious deterioration in health of the subject that, 1) resulted in a life-threatening illness or injury, 2) resulted in a permanent impairment of a body structure or a body function, 3) required in-patient hospitalization or prolongation of existing hospitalization, 4) resulted in medical or surgical intervention to prevent permanent impairment to body structure or a body function; c) To fetal distress or a congenital abnormality or birth defect. May be anticipated or unanticipated. **EN ISO 14155. Clinical investigation of medical devices for human subjects – Good Clinical Practice*	All adverse events not reported as serious. At each visit, all adverse events observed by the investigator/designate or reported by subject must be evaluated and recorded on an adverse event form. A non-serious adverse event is further classified with respect to severity and relationship to the trial product. A non-serious adverse event may be anticipated or unanticipated. Further classification with regard to severity • Mild: Transient symptoms, easily tolerated, no interference with subjects daily activities. • Moderate: Marked symptoms, moderate interference with subjects daily activities, and tolerable. • Severe: Considerable interference with subject's daily activities, not tolerable.
Relationship to trial product: • Definitely Related: Causal relationship has been established and documented • Probably Related: Good reasons and sufficient documentation to assume causal relationship have been established • Possibly Related: Causal relationship is likely and cannot be excluded • Probably Not Related: Good reasons and sufficient documentation not established to assume causal relationship • Not Related: The event is most likely related to an etiology other than the trial treatment	

7.3.2 **Reporting of Adverse Events in the US:**

1. The Investigator or designee will notify the Study Manager or Monitor within 24 hours of any Serious Adverse Event that occurred during the study. The sponsor will promptly review all information relevant to the safety of the investigational device. The information must be provided by phone or fax to:

[redacted]

2. The investigator or designee must notify the sponsor and reviewing IRB by phone or fax of Unanticipated Serious Device-Related Adverse Events within 24 hours of learning of the event, followed by a written a report within 10 working days after learning of the event.
3. Upon receipt of a report of an UADE by the Ascensia Diabetes Care Study Manager or Monitor, the report will be immediately forwarded to the Ascensia Diabetes Care Medical Director, [redacted] email address: robert.morin@ascensia.com).
4. The sponsor (Ascensia Diabetes Care) must report Unanticipated Adverse Device Effects (UADE) to the FDA, all participating investigators, and reviewing IRBs within 10 working days after the sponsor first receives notice of the event.
5. Regardless of the above definitions, any additional adverse experience that the investigator considers serious, and/or of concern in relationship to the study must be documented and reported to the Study Manager or Monitor within 24 hours.
6. All non-serious adverse events will be reported to the IRB in the study closeout correspondence to the IRB.

7.4 Medical Device Reporting (MDR)

If an adverse event occurs that is directly caused by a marketed product used in the study, the adverse event should be reported immediately, but in any case within 24 hours, to the Customer Service Department [redacted] Also contact the Ascensia Diabetes Care representative listed in Section 12.0.

8.0 STUDY TERMINATION CRITERIA

Criteria to Withdraw Subject from Study

Subjects may be withdrawn from the study at their own request for any reason at any time.

Subjects may be withdrawn at the discretion of the Investigator for one of the following reasons:

- Adverse Event
- Subject non-compliance with protocol requirements

- Other, at the discretion of the investigator

Data collected from withdrawn subjects will be analyzed as appropriate and results retained for safety assessments.

Data will not be retained in analyses related to the primary objective of the study if there is a valid reason to believe that the data may be biased, incorrect or confounded.

9.0 REGULATORY

Regulatory Status of the System

The Contour Next One meter and Contour Diabetes App 1.0 (which is a simpler version of this App) have CE-mark, but may still be investigational in the US. The Contour Diabetes App 2.0 which is the focus of this study will be investigational at the time of the study. In addition to the regulations outlined in the Ascensia Diabetes Care Global Clinical Affairs standard operating procedures, this protocol also complies with the clinical trial regulations of British Standard BS EN 13612:2002, and "Performance evaluation of in vitro diagnostic medical devices", GCP ISO 14155.

Institutional Review Board Approval

An Institutional Review Board (IRB) must approve this protocol, the Informed Consent (IC) document and any other supporting study documents which impact subject safety, prior to study initiation. The investigational site may not begin the study until the IRB has given its written and dated approval via a letter that identifies the version/date of the protocol and Informed Consent Form (ICF). A copy of the approval letter and the approved ICF must be provided to the Investigator and to Ascensia Diabetes Care prior to the Study Initiation Visit.

Informed Consent Requirement

Each subject must provide informed consent before she/he can participate in the study. The informed consent process fully apprises the subjects of the risks and benefits to them and to society for participating in the study. The ICF will clearly state that designated study personnel will be able to view the subject's medical information. The ICF will also state that Ascensia Diabetes Care representatives may observe some subjects as part of study staff training, study monitoring or for troubleshooting problems with the investigational devices. If the subject understands and agrees to participate in the study, he/she will sign the ICF and then it will be signed by the person conducting the informed consent process. All subjects will be given a copy of the ICF. If a subject has a question about his/her rights, he/she may contact a member of the IRB at any time during or after study participation.

Study Documentation and Procedures

The investigator will keep study records for a minimum of three years. If the investigator is unable to store the documents for the required time, other arrangements may be made with Ascensia Diabetes Care.

Investigational Devices

The investigational Contour Diabetes App 2.0 will be un-installed from the subjects' mobile device at Visit 2, after the subject has completed the study. The Contour Next One meters, UGs and QRGs are for investigational use only and must be accounted for and returned to Ascensia. Jane Wallace, Study Manager, is responsible for oversight of tracking of investigational materials. All

meters should be disinfected per Appendix B prior to shipping back to Ascensia Diabetes Care.

Study Monitoring

The study will be monitored by Ascensia Diabetes Care personnel or designee(s). A monitoring plan will be completed by the Study Manager/Study Monitor prior to the study. The study monitor or designee will conduct a study initiation visit, at least 1 monitoring visit, and a close out visit. (Note: the latter two visits may occur within a continuous timeframe).

Ascensia Diabetes Care representatives or a designee may observe some subject visits as part of study staff training, study monitoring or for troubleshooting problems with the investigational devices. Ascensia Diabetes Care representatives will maintain subject confidentiality and will not interfere with the rights of human subjects or with their safety or bias study conduct.

Site staff will correspond with Study Manager daily during the enrollment phase, reporting the status of subject enrollment, by providing subject ID and subject study email address (de-identified) so the Ascensia Diabetes Care administrator can verify the setup profile was initiated successfully.

Investigator's Report of Study Closure

The Ascensia Diabetes Care Study Manager or designee will send a letter to the site informing them that the study is closed. The study will be considered closed when the data has been locked for data analysis.

The Investigator or designee will submit a report summarizing subject disposition and other study details, as appropriate, to the Ascensia Diabetes Care Study Manager and the reviewing IRB/EC. This report will be completed within 3 months of the study closure date.

In addition, the Ascensia Diabetes Care Study Manager or designee will report the completion of the study to the IRB within 6 months of study closure.

Registration of Trial

The trial will be registered with clinicaltrials.gov as required.

10.0 DATA COLLECTION AND MANAGEMENT

A unique number will identify each subject. The unique number will be the only identifying information entered. A master list of subject names, with their subject IDs, will be kept by the Investigator at the study site. The Investigator will retain all signed IC documents.

Study data will be recorded on paper forms that will serve as source documents. These data will be entered by the site staff (or designee) into an Electronic Data Capture (EDC) system provided by Ascensia Diabetes Care. In addition to data collection, the EDC system will be used for data cleaning as well as monitoring operations. Site and sponsor users will be trained on the system prior to the study start at their site, and their access to EDC system will be contingent upon successful completion of training requirements. Study personnel will complete and sign all appropriate source document forms in compliance with Good Clinical Practice (GCP). Source documents (Forms) should be completed legibly, in black or blue ink. If it is necessary to make corrections, a single line should be drawn through the original entry, the new entry written in, and the correction initialed and dated by the individual making the correction.

The original forms will be retained by the Investigator for a minimum of three years.

The Investigator or designee will sign and date an Adverse Event Form for each Adverse Event experienced by any subject.

Data Downloaded from the Cloud

Additionally, apart from the data collected, then entered into EDC, de-identified data collected in the Contour Diabetes App will be uploaded to the Cloud throughout the study into a US server (US site data). At the end of the study the cloud data will be downloaded to an Ascensia Diabetes Care database. This downloaded cloud data will be able to be accessed by Ascensia Diabetes Care engineering group and Ascensia Diabetes Care Global Medical/Clinical Affairs personnel. Summaries of the cloud data will be included in the Final Clinical Study Report and Statistics Reports. The downloaded data will include the following information, all of which are anonymous, de-identified subject data:

- Subject study email address
- Meter serial number
- Meter and manually entered blood glucose readings with associated dates, times and meal markers
- Settings: target ranges, low, high, and critical lows and highs
- Entries such as notes, exercise (type and duration), food
- Smart Reminders – record of reminders set by the subject
- Record of pattern notifications including pattern type, dates, times, and pattern status indicators.

The following will not be saved and included in the study database: subject emergency contact name, phone number or any other identifying information.

11.0 STATISTICAL METHODS AND ANALYSIS

An n = 40 responses yields approximately a 93.3% chance of "passing" the primary objective criteria if there is an 85% probability that a randomly selected person could perform the critical tasks successfully.

Performance Criteria for subject's success at utilizing system features**:**

There is at least an 85% probability that any user would be able to utilize the App features with success. A hypothesis test will be performed to test the hypotheses for each feature individually:

$$H_0 : \Pr\{user\ can\ perform\ \ a\ given\ \ basic\ task\ \ successfully\} < 85\%$$

against:

$$H_1 : \Pr\{user can perform a given basic task\ successfully\} \geq 85\%$$

With n = 40 responses, we must observe at least 31 responses with a 1, 2, or 3 score on a critical questionnaire statement (statements 1, 8, 9, and 42 as shown in Appendix A) to reject the null hypothesis, H_0. This criterion yields the following risk characteristics:

There is approximately a 93.3% chance (power) of obtaining at least 31 "successes" out of n = 40 responses IF the actual probability of success is 85%. Conversely, there is approximately a 90% chance of failing to obtain at least 31 successes out of n = 40 responses IF the actual probability of success is only about 66.8%.

It is likely that the actual sample size will not be exactly 40, but in fact may be slightly higher or lower. Responses of "no opinion" will not be counted for any hypothesis test. The critical values for hypothesis tests will be adjusted for sample size, to maintain approximately the same power characteristics, i.e., the probability of rejecting the null if the success probability is 85% will be kept to be no greater than 95%.

The results accessing each feature will be evaluated independently. Statements 1, 8, 9, and 42 in Appendix A correspond to the primary endpoint and the 85% criterion.

Cluster Analyses and Other Associated Analyses

Ordinal-scaled variables from ease of use and diabetes management attitude surveys will be used in a k-means cluster analysis, to assess the possibility of unknown groupings (clusters) of subjects within the study sample. Other variables, such as diabetes type, age, gender, and frequency of blood glucose testing will be used to potentially further characterize the groupings. Inasmuch as there is no a priori expectation for the numbers of clusters, nor is there any expectation or hypotheses that any variables will have associations with clusters, these analyses should be considered exploratory.

A condition of hardware/software failure that cause or contribute to a subject's inability to access or utilize any given feature will be considered an un-evaluable observation. (i.e., will not be included in the numerator/denominator for calculating percentage of user success.)

Frequency distributions of scores will be provided for the other variables, i.e., subjects' ratings on ease of use and subjects' ratings on clarity/utility of user instructions, subjects' opinions about their use of the Contour Diabetes App 2.0 system. Correlation coefficient, and associated 95% two-sided confidence interval, will be computed for laboratory HbA1c versus average glucose. Average glucose will be computed from cloud data.

Histograms for the change in HbA1c, fructosamine, weight, and total daily insulin (as reported by subjects) from visit 1 to visit 2 will be constructed. ANOVA (or equivalent method) will be used to determine whether change in HbA1c, Fructosamine, weight, and total daily insulin are significantly different from zero. P-values less than or equal to 0.05 will be considered significant. Confidence intervals (95%, two-sided) for the average change in HbA1c, fructosamine, weight, and total daily insulin dose will be computed.

Average daily utilization rates for selected App features will be computed, together with 95% (non-simultaneous) confidence intervals. Frequency tables for discrete demographic variables will be constructed. Descriptive statistics, such as mean, standard deviation, median, minimum, maximum will be computed for continuously-valued demographic variables (e.g., subject age).

12.0 ADMINISTRATION

All investigator and site staff communications regarding the study should be directed to the Ascensia Diabetes Care Study Manager. If at any time questions or problems arise concerning the evaluation, please contact the Ascensia Diabetes Care Study Manager at the telephone number listed below:

Documents to be collected prior to the start of the study include, but are not limited to:

- CV(s) of Investigator(s) and Sub-Investigators
- Signature(s) of PI on protocol
- Letter of IRB approval
- IRB approved ICF
- Financial Disclosures for PI and Sub-Investigators
- Ascensia Diabetes Care Clinical Trial Agreement
- Investigator's Agreements for Sub-Investigators
- Staff GCP training documentation – this will be requested at study initiation visit.

Data / documents to be collected during or after completion of the study:

- EDC database
- Progress Notes
- Signature and Delegation Log (for all study staff)
- Investigator's Report of Study Closure and IRB acknowledgement
- Study related-training documentation

Appendix A – Contour Diabetes App 2.0 Questionnaire

Obtain a synced blood glucose reading

1. Overall, I was able to successfully sync my blood glucose value on the meter with the App.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

2. Overall, I am satisfied with how easily my blood glucose value on the meter syncs with the App.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

3. The syncing of my blood glucose value from the meter to the App is reliable.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

4. The syncing of my blood glucose value from the meter to the App is accurate.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

5. Did you change time zones during the study? Yes or No

6. If Yes, did the App adjust to the time zone change as expected or did you experience any problems? Please comment below.

(open text field)

7. Do you have any comments about syncing of the meter with the App?

(open text field)

Access and interpret glucose displays such as expanded graph and sequential views.

8. Overall, I was able to successfully access glucose displays such as Expanded Graph view and My Readings view in the App.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

9. Overall, I was able to successfully interpret glucose displays such as Expanded Graph view and My Readings view in the App.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

10. Accessing the Expanded Graph view was:

1= Very Simple

2= Simple

3= Neither Simple nor Difficult

4= Difficult

5= Very Difficult

No opinion

11. Using the Expanded Graph view was:

1= Very Simple

2= Simple

3= Neither Simple nor Difficult

4= Difficult

5= Very Difficult

No opinion

12. Expanded Graph View in the App was understandable and easy to interpret.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

13. Expanded Graph View in the App was helpful for me in managing my diabetes.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

14. Accessing the My Readings view was:

1= Very Simple

2= Simple

3= Neither Simple nor Difficult

4= Difficult

5= Very Difficult

No opinion

15. Using the My Readings view was:

1= Very Simple

2= Simple

3= Neither Simple nor Difficult

4= Difficult

5= Very Difficult

No opinion

16. My Readings View in the App was understandable and easy to interpret.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

17. My Readings View in the App was helpful for me in managing my diabetes.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

18. I was able to successfully access the Edit view in the App.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

19. Using the Edit view was:

1= Very Simple

2= Simple

3= Neither Simple nor Difficult

4= Difficult

5= Very Difficult

No opinion

20. I think using the Edit view became easier to use after multiple uses.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

21. Using the Meal Marker selection screen was:

1= Very Simple

2= Simple

3= Neither Simple nor Difficult

4= Difficult

5= Very Difficult

No opinion

22. Meal Marking in the App was helpful for me in managing my diabetes.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

23. I think Meal Marking became easier to use after multiple uses of the App.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

24. I found that Meal Marking in the App was useful and I would be likely to use in the future.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

25. I used the Manual Blood Glucose Entry Screen in the App.

Yes or No

If 'No' go to Question 27.

26. Using the Manual Blood Glucose Entry screen was:

1= Very Simple

2= Simple

3= Neither Simple nor Difficult

4= Difficult

5= Very Difficult

No opinion

27. Do you have any comments about the glucose displays, meal marking or using the Edit View in the App?

(open text field)

Clarity Of User Instructions

28. The instructions in the short videos and informational screen shots of the App are understandable.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

29. The short videos and informational screen shots were helpful to me in using the App.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

30. The Help section found in the App was helpful to me in using the App.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

31. Do you have any comments about the instructional materials provided with the system?

(open text field)

Recognition of glucose pattern messages

32. The App notified me of some identified blood glucose patterns.

Yes No

If Yes continue to Question **33.** If No, skip to Question **42.**

33. The information I learned through my blood glucose pattern messages in the App was understandable and I was able to interpret them.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

34. The information I learned through my blood glucose pattern messages was useful / helpful for me in managing my diabetes.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

35. I found the ability to adjust the frequency of the pattern messages helpful.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

36. I think the App showed me too many pattern messages.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

37. I think the App showed me just the right number of pattern messages.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

38. I was able to successfully access Pattern Manager view in the App..

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

39. The Pattern Manager view was helpful to me in managing my diabetes.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

40. I would be likely to use Pattern Manager in the App in the future.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

41. Do you have any comments about the glucose pattern messages or the pattern manager in the App? *(open text field)*

Use of "Smart Reminders"

42. I was able to successfully access and use the "Smart Reminders" feature in the App.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

43. Accessing the Smart Reminders feature was:

1= Very Simple

2= Simple

3= Neither Simple nor Difficult

4= Difficult

5= Very Difficult

No opinion

44. Using the Smart Reminders feature was:

1= Very Simple

2= Simple

3= Neither Simple nor Difficult

4= Difficult

5= Very Difficult

No opinion

45. I found Smart Reminders test plans that were helpful to me.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

46. I followed the Smart Reminders test plans.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

47. Smart Reminders in the App were useful / helpful for me in managing my diabetes.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

48. I would be likely to use the Smart Reminders feature in the App in the future.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

49. Do you have any comments about the Smart Reminders feature in the App?

(open text field)

Other Questions

50. When using health apps, privacy is a very important concern for me.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

51. My blood glucose value appearing on my smart phone is not a privacy concern for me. (For example, someone else viewing my BG results on my smart phone is not a concern for me.)

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

52. Do you have any comments about privacy when using health apps?

(open text field)

53. This BGM/App System will provide me with a better understanding of my disease.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

54. This BGM/App System helped me feel more engaged with my diabetes management program.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

55. Using this BGM/App System, I felt more motivated to adhere to my health care provider's therapy and testing recommendations.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

56. Using this BGM/App System, I found myself testing more frequently throughout the day.

1= Strongly Agree

2= Agree

3= Neither Agree nor Disagree

4= Disagree

5= Strongly Disagree

No opinion

57. What could make you want to use the Contour Next One system and App more frequently? Please comment *(open text field)*

58. Is there anything in the Contour Next One system and App which causes you to not want to use the system? Please comment. *(open text field)*

59. Do you have any other comments about the BGMs/ App system?*(open text field)*

Appendix B - Instructions for Cleaning and Disinfecting Meters

Single use items, such as test strips, test strip vials or lancing devices, shall not be used with multiple subjects. Blood glucose meters and similar devices shall be cleaned and disinfected using an EPA-registered disinfectant that is suitable for use on hard, non-porous surfaces. See http://oaspub.epa.gov/pestlabl/ppls.home for a list of EPA-registered disinfectants, or search http://ppis.ceris.purdue.edu. The list includes products such as the following.

EPA Registration	Manufacturer	Product Name	Active Ingredient
67619-12	Clorox Professional Products Company	Clorox Germicidal Wipes	0.55% sodium hypochlorite
9480-6	Professional Disposables International	PDI Sani-Cloth PLUS	0.25% quaternary ammonium chlorides 14.85% isopropanol
67619-25	Clorox Professional Products Company	Hydrogen Peroxide Cleaner Disinfectant Wipes	1.4% hydrogen peroxide
56392-7	Caltech	Dispatch Hospital Cleaner Disinfectant	0.55% sodium hypochlorite

1. Follow the manufacturer's directions printed on the container. Wear gloves.
2. If the meter is soiled, clean before disinfecting.
3. Disinfect by wiping the meter until wet. Take care to prevent solution from running into the test strip port or around the buttons.
4. Allow the meter to remain wet for the contact time indicated on the disinfectant product label.
5. After the indicated contact time has elapsed, wipe dry with a clean paper towel.
6. Allow the meters to air dry for at least 2 hours before using the meter again.
7. Dispose of all materials used in the cleaning and disinfecting procedure according to current lab biohazard procedures.

References

CLSI. Protection of laboratory workers from occupationally acquired infections; approved guideline – third edition. CLSI document M29-A3. ISBN1-56238-567-4.

Rutala W, Weber D, Healthcare Infection Control Practices Advisory Committee. Guideline for disinfection and sterilization in healthcare facilities, 2008. CDC.

FDA, Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, May 2, 2011.

Appendix C – Schedule of Events

Event	**Screen**	**App Use Run-In**		**Patterns Activated (Auto)**		
	Visit 1	Day 0 (Visit 1)	Approx Day 14	Day 15	Approx Day 28	Approx Day 42 (Visit 2)
Procedural						
Informed Consent	X					
Medical History*	X					
Determine Eligibility	X					
Body Weight/Height		X				X
Office Visit	X	X				X
Notify personal health care provider of study participation		X				
Receive study supplies		X				
Download App to Smart Device, pair with meter, setup app profile		X				
Perform BG test, upload meter results, sync with Cloud		X				
Telephone Contact			X		X	
Return with meter, UG, mobile device. • Assure meter is synced to the App. • Verify and record mobile device software						X
Safety						
Capture Adverse Events			X		X	X
Severe Hypoglycemic Episode History			X		X	X
Hospitalization History**			X		X	X
Determine Total daily insulin dose (self reported)		X	X		X	X
Endpoints						
HbA1c		X				X
Fructosamine		X				X
User Questionnaire						X

Feature Utilization Rate***						X
User Feedback on Failures/Unexpected events			X		X	X
Uninstall App from mobile device						X
* Medical History Screen applies to Inclusion Exclusion criteria only for purposes of eligibility						
** History of hospitalization from last telephone contact or office visit to include main reason for admission.						
*** Feature Utilization Rate will be computed from cloud downloaded data post-study						