Pilot Study 3 of Outpatient Control-to-Range: Safety and Efficacy with Day-and-Night In-Home Use
Extended Closed-Loop at Home Contact Information

Identifying Information

PtID	**1. Patient ID: CTR3-____ ____ ____- ____ ____ ____ ____**
Namecode	**2. Initials: ____ ____ ____**

ExtendedPhoneContact

Contact Information

PhCallDt	**1. Contact Date: ___ ___ / ___ ___ /___ ___ mm/dd/yy**
NonPContType	**2. Mode of Communication:** ☐ Phone ☐ Text ☐ Email ☐ Office Visit
PrsnSpk	**3. Person contacted:** ☐Subject ☐Other
PrsnSpkDs	**If Other, complete the following:** **Relationship to Subject: _____**
CallerID	**4. ID of Person Contacting Subject: ___ - ___ ___ ___**

Prior to completion of the contact during the initial trial period, the subject's data from previous day and night or week must be reviewed.

Closed-Loop Data Review

SystemProblems **SystemProblemsDs**	**1. Did the subject have any significant problems with the system such as:**) Receiving any significant error messages related to meal bolusing, CGM calibration announcement, etc.) Responding to system alert messages) Extended loss of communication with remote monitoring) Other aspects of the system operation ☐Yes ☐No **1a. If Yes, please describe:** _____ _____ _____ _____
MeterHighOrLow	**2. Did the subject have any occurrences of BG meter readings <50 mg/dl or >400 mg/dl in the absence of any infusion set failure?** ☐Yes ☐No

MeterHighOrLowDs	**2a. If Yes, please describe:** _____ _____ _____ _____
IssuesDiscussed **IssuesDiscussedDs**	**3. Were all of the following issues regarding appropriate use of the study system discussed?**) Timely Response to system alarms and appropriate treatment of hypo- and hyperglycemia) Avoiding deviating from his/her regular daily routine in regard to diet and exercise and maintaining his or her usual sleep schedule) Avoiding consuming more than 3 alcoholic drinks in any one day) Performing a fingerstick BG at least 7 times daily (before meals, about 2 hours after meals and at bedtime)) Use of Safety Mode during exercise or when operating a motor vehicle) Avoiding use of closed-loop mode during periods of illness, travel, time away from care partner, or during periods of use of medications such as epinephrine for the emergency treatment of a severe allergic reactions or asthma attack in addition to use of oral or injectable glucocorticoids) Advisability of the use of a highly effective means of contraception ☐**Yes** ☐**No** **a. If No, please describe:** _____ _____ _____ _____ _____

Adverse Events Since Last Contact

SevHypo	**1. Did the subject have a severe hypoglycemic episode requiring assistance of another person to administer carbohydrate, glucagon or other resuscitative actions not already reported?** ☐Yes ☐No (If Yes, complete an Adverse Event Form)
SevHyper	**2. Did the subject have a severe hyperglycemic event resulting in DKA not already reported?** ☐Yes ☐No (If Yes, complete an Adverse Event Form) DKA is defined as follows by the DCCT, and has all of the following:) Symptoms such as polyuria, polydipsia, nausea, or vomiting;) Serum ketones or large/moderate urine ketones;) Either arterial blood pH <7.30 or venous pH <7.24 or serum bicarbonate <15; and) Treatment provided in a health care facility

AdverseEvent	**3. Have any adverse events or any unexpected medical occurrence that is study or device related occurred that has not already been reported?** ☐Yes ☐No (If Yes, complete an Adverse Event Form)