Pilot Study 3 of Outpatient Control-to-Range: Safety and Efficacy with Day-and-Night In-Home Use
Visit 6- 24-Hour Closed-Loop Debrief Visit

Identifying Information

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

Visit Information

VisitDt	**1. Visit Date: ___ ___ / ___ ___ /___ ___ mm/dd/yy**
InvID	**2. Study ID of Investigator: ___ - ___ ___ ___**

DayAndNightEnd

Subject Questionnaire and Structured Interview

QuestionnaireCompleted	**Did the subject and care giver complete the DiAs Questionniare and Clarke Hypoglycemia Awareness Questionnaire?** ☐Yes ☐No **(Please comment below)**
QuestionnaireCompletedDs	**Comment:** _____ _____ _____ _____

StudySuppliesReturned	**Were all system study supplies returned?** ☐Yes ☐No ***(Please comment below)***
StudySuppliesReturnedDs	**Comment:** _____ _____

_____
_____

Adverse Events Since Last Contact

SevHypo

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 a Severe Hypo Event Form)**

Did the subject have a DKA not already reported?

☐Yes ☐No **(If Yes, complete a DKA Event Form)**

SevHyper

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**

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)**

AdverseEvent

If subject had severe hypoglycemia or DKA, the subject is no longer eligible to continue in the study. Please complete a Final Status form.

If there have been any changes made in insulin therapy, please submit the changes in the Insulin Therapy Form.