

Pilot Study 3 of Outpatient Control-to-Range: Safety and Efficacy with Day-and-Night In-Home Use
Visit 5- Overnight Only Closed-Loop Debrief Visit

Table: **tblCTR3OvernightEnd**

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: ____ - _____

Urine Testing *(Only required if female)*

PregTestDt	1. If subject is female, a. Date of negative urine pregnancy test: ____ / ____ / ____ mm/dd/yy (If not done indicate reason below)
PregTestNotDoneMF	ai. If not done, why: <i>Dropdown list (Premenstrual, Surgically sterile, Male, Other)</i>
PregTestNotDoneDs	aii. If reason is 'Other,' please describe: _____ _____

Eligibility Assessment

SubEligibility	<input type="checkbox"/> The subject met the criteria for successful system use during the Two-Week Overnight-Only Closed-Loop Home Use Period and can continue to home use of the system in 24-hr closed-loop configuration.
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Medical History

PreExistMedCond

1. Have there been any new medical problems not previously recorded on the Medical Condition Form?

☐ Yes ☐ No (If Yes, please update the Medical Condition Form.)

Concomitant Medications

ConComMed

1. Have there been any changes in medications not previously recorded on the Medications Form?

☐ Yes ☐ No (If Yes, please update the Medications Form.)

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 an Adverse Event Form)

Did the subject have a DKA not already reported?

☐ Yes ☐ No (If Yes, complete an Adverse 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

AdverseEvent

Have any adverse events or any unexpected medical occurrence occurred that has not already been reported?

☐ Yes ☐ No (If Yes, complete an Adverse Event Form)

