

**Pilot Study 3 of Outpatient Control-to-Range: Safety and Efficacy with Day-and-Night In-Home Use
Visit 4- Initiation of Trial Overnight Closed-Loop At Home**

Table: tblCTR3OvernightTrial

1.1 Synopsis:

After successful 48-hour Transitional Training, the subject will initiate a 2-5 day trial period of home use of the system in overnight-only closed-loop configuration during which remote monitoring will be in place. The subject will be instructed to activate closed-loop operation each evening any time between just before eating dinner and prior to bedtime, with the expectation that the subject will remain at home after initiating closed-loop operation. The subject will be instructed to switch back to open-loop mode upon waking up in the morning.

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: ____ - _____

Closed-Loop Supplies

DiAsSN	1. DiAs Serial Number: _____
TranslatorBoxSN	2. Translator Box Serial Number: _____ <input type="checkbox"/> N/A, no translator box used
TranslatorBoxNotUsed	
DexcomReceiverSN	3. Dexcom Receiver Serial Number: _____ <input type="checkbox"/> N/A, no receiver used
DexcomReceiverNotUsed	
DexcomTransmitterSN	4. Dexcom Transmitter Serial Number: _____

Home Use Device Preparation

ClosedLoopPartiallyDisabled	5. Was Closed-Loop operation disabled during the day on the DiAs system? <input type="checkbox"/> Yes <input type="checkbox"/> No
ClosedLoopPartiallyDisabledDs	a. If No, please indicate why not: _____
QCMeter	6. Was QC testing successful with the study blood glucose meter using two different concentrations of control solution? <input type="checkbox"/> Yes <input type="checkbox"/> No
QCMeterDs	a. If No, please indicate why not: _____
QCKetone	7. Was QC testing successful with the study blood ketone meter using two different concentrations of control solution? <input type="checkbox"/> Yes <input type="checkbox"/> No
QCKetoneDs	

	<p>a. If No, please indicate why not:</p> <hr/> <hr/>
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