

**Pilot Study 3 of Outpatient Control-to-Range: Safety and Efficacy with Day-and-Night In-Home Use**  
**Visit 5- Initiation of Trial 24-Hour Closed-Loop At Home**

### 1.1 Synopsis:

The subject will initiate a 2-5 day trial period of home use of the system in 24-hour closed-loop configuration during which remote monitoring will be in place. The subject will be instructed to use the system in a closed-loop mode except when no calibrated CGM sensor is available. The subject will be instructed to perform a fingerstick and switch the system to Safety Mode prior to exercising or engaging in potentially dangerous activities such as operating a motor vehicle or operating heavy machinery. When exercising, the subject will be instructed to limit activity to no more than one hour at no more than a moderate level of intensity.

#### Identifying Information

<b>PtID</b>	1. Patient ID: CTR3-____-____
<b>Namecode</b>	2. Initials: ____

#### Visit Information

<b>VisitDt</b> <b>InvID</b>	1. Visit Date: ____/____/____ mm/dd/yy
	2. Study ID of Investigator: ____-____

#### Subject DiAs Training

<b>TrainingReceived1</b>	<input type="checkbox"/> Subject received 24-hr closed-loop system training per protocol.
<b>TrainingReceived2</b>	<input type="checkbox"/> The subject was instructed to use the system in closed-loop mode except when no calibrated CGM sensor is available and to switch to Safety Mode when engaging in potentially dangerous activities such as

	operating a motor vehicle or heavy machinery or engaging in extreme sports.
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#### Home Use Device Preparation

<p>ClosedLoopFullyEnabled</p> <p>ClosedLoopFullyEnabledDs</p> <p>QCMeter</p> <p>QCMeterDs</p> <p>QCKetone</p> <p>QCKetoneDs</p>	<ol style="list-style-type: none"> <li>Is Closed-Loop operation set to be fully functional during day and night on the DiAs system? <input type="checkbox"/>Yes <input type="checkbox"/>No             <ol style="list-style-type: none"> <li>If No, please indicate why not: _____</li> </ol> </li> <li>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             <ol style="list-style-type: none"> <li>If No, please indicate why not: _____</li> </ol> </li> <li>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             <ol style="list-style-type: none"> <li>If No, please indicate why not: _____</li> </ol> </li> </ol>
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