

# Enrollment Visit

## Visit Information Section

	1. Name of Investigator _____
VisitDt	2. Visit Date: _____

## Identifying Information

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

## tblEnrollment

### Eligibility [SubEligibility](#)

<p>Verify that subject meets all of the following eligibility criteria and none of the exclusion criteria.</p> <p><b>Eligibility</b></p> <ul style="list-style-type: none"><li><input type="checkbox"/> Clinical diagnosis of type 1 diabetes for at least 1 year</li><li><input type="checkbox"/> Using daily insulin therapy for at least 1 year</li><li><input type="checkbox"/> Using an insulin infusion pump for at least 6 months</li><li><input type="checkbox"/> Age 18 - &lt;70 years</li><li><input type="checkbox"/> HbA1c &lt;10.0%; if HbA1c &lt;6.0% then total daily insulin must be &gt;0.5 U/kg</li><li><input type="checkbox"/> For females, not currently known to be pregnant- If female and sexually active, must agree to use a form of contraception to prevent pregnancy while a participant in the study. A negative urine pregnancy test will be required for all premenopausal women who are not surgically sterile. Subjects who become pregnant will be discontinued from the study.</li></ul>
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- ☐ Demonstration of proper mental status and cognition for the study
- ☐ Currently using insulin-to-carbohydrate ratio to calculate meal bolus sizes
- ☐ Hypoglycemia awareness as demonstrated by a Clarke Hypoglycemia Awareness score of 2 or lower
- ☐ Access to internet and cell phone service at home
- ☐ Living with significant other or family member committed to participating in all training activities, knowledgeable at all times of the participant's location, and being present and available to provide assistance when system is being used at night
- ☐ Commitment to maintaining uninterrupted availability via cell phone and avoiding any overnight travel for the duration of the each two-week period while using the closed-loop system
- ☐ An understanding and willingness to follow the protocol and sign the informed consent

**Exclusion - Check all that DO NOT apply**

- ☐ Admission for diabetic ketoacidosis in the 12 months prior to enrollment
- ☐ Severe hypoglycemia resulting in seizure or loss of consciousness in the 12 months prior to enrollment
- ☐ History of seizure disorder (except for hypoglycemic seizure), unless written clearance is received from neurologist
- ☐ Coronary artery disease or heart failure, unless written clearance is received from a cardiologist
- ☐ History of cardiac arrhythmia (except for benign premature atrial contractions and benign premature ventricular contractions which are permitted)
- ☐ Cystic fibrosis
- ☐ A known medical condition that in the judgment of the investigator might interfere with the completion of the protocol such as the following examples:
  - ) Inpatient psychiatric treatment in the past 6 months for either the subject or the subject's primary care giver (i.e., parent or guardian)
  - ) Presence of a known adrenal disorder
  - ) Abnormal liver function test results (Transaminase >2 times the upper limit of normal); testing required for subjects taking medications known to affect liver function or with diseases known to affect liver function
  - ) Abnormal renal function test results (calculated GFR <60 mL/min/1.73m<sup>2</sup>); testing required for subjects with diabetes duration of greater than 5 years post onset of puberty
  - ) Active gastroparesis
  - ) If on antihypertensive, thyroid, anti-depressant or lipid lowering medication, lack of stability on the medication for the past 2 months prior to enrollment in the study

<ul style="list-style-type: none"> <li>)</li> <li>)</li> <li>)</li> <li><input type="checkbox"/></li> <li><input type="checkbox"/></li> <li>)</li> <li>)</li> <li>)</li> <li>)</li> </ul>	<p><b>Uncontrolled thyroid disease (TSH undetectable or &gt;10 mIU/L); testing required within three months prior to admission for subjects with a goiter, positive antibodies, or who are on thyroid hormone replacement, and within one year otherwise</b></p> <p><b>Abuse of alcohol or recreational drugs</b></p> <p><b>Infectious process not anticipated to resolve prior to study procedures (e.g. meningitis, pneumonia, osteomyelitis)</b></p> <p><b>A recent injury to body or limb, muscular disorder, use of any medication, any carcinogenic disease, or other significant medical disorder if that injury, medication or disease in the judgment of the investigator will affect the completion of the protocol</b></p> <p><b>Current use of the following drugs and supplements:</b></p> <p><b>Acetaminophen</b></p> <p><b>Any medication being taken to lower blood glucose, such as Pramlintide, Metformin, GLP-1 Analogs such as Liraglutide, and nutraceuticals intended to lower blood glucose</b></p> <p><b>Beta blockers</b></p> <p><b>Any other medication that the investigator believes is a contraindication to the subject's participation</b></p>
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#### Demographic Information

<b>Gender</b>	<p><b>1. Gender:</b>    <input type="checkbox"/> Male    <input type="checkbox"/> Female</p>
<b>Ethnicity</b>	<p><b>2. Ethnicity:</b>    <input type="checkbox"/> Hispanic or Latino    <input type="checkbox"/> Not Hispanic or Latino    <input type="checkbox"/> Unknown/not reported  <i>See "Personal Census Data" for definitions</i></p>
<b>Race</b>	<p><b>3. Race:</b>    <input type="checkbox"/> White    <input type="checkbox"/> Black/African-American    <input type="checkbox"/> Native Hawaiian/Other Pacific Islander    <input type="checkbox"/> Asian    <input type="checkbox"/> American Indian/Alaskan Native    <input type="checkbox"/> More than one race  <input type="checkbox"/> Unknown/not reported    <input type="checkbox"/> If more than one race selected please specify:</p>

#### Diabetes History

<b>DiabetesDt</b>	<p><b>1. Date of diagnosis of type 1 diabetes:</b> ____ ____ / ____ ____ mm/yy</p>
<b>HypoEvent</b>	<p><b>2. Did the subject have a hypoglycemic seizure/loss of consciousness in the last 12 months?</b>  <input type="checkbox"/> Yes    <input type="checkbox"/> No</p>
<b>ClarkeScore</b>	<p><b>3. Clarke Hypoglycemia Awareness Score:</b> ____ ____ <i>(Please complete the Clarke Hypoglycemia Awareness Questionnaire)</i></p>

## Hemoglobin A1c

<b>HbA1CTestDt</b>	1. Date of Test: ____ / ____ / ____ mm/dd/yy
<b>HbA1CTest</b>	2. HbA1C: ____ . ____ %
<b>HbA1CTestMethod</b>	3. Method in which HbA1c was obtained: <i>Dropdown list</i>
	3a. If Other please specify: _____

## Insulin Use

<b>DailyIns</b>	1. Total daily insulin: ____ Units ( <i>Average over one week</i> )
<b>DailyBasal</b>	2. Total daily basal: ____ Units ( <i>Average over one week</i> )
<b>Novolog</b>	3. Current insulin used: <i>Check all that apply</i>
<b>Humalog</b>	<input type="checkbox"/> Novolog <input type="checkbox"/> Humalog <input type="checkbox"/> Regular <input type="checkbox"/> Apidra <input type="checkbox"/> Other
<b>Regular</b>	
<b>Apidra</b>	
<b>InsTypeOther</b>	3a. If Other please specify: _____
<b>InsPumpType</b>	4. Pump currently being used: _____

## Physical Examination

<b>Weight</b>	1. Weight: ____ . ____ kg
<b>Height</b>	2. Height: ____ . ____ cm
<b>BldPrSys</b>	3. Blood Pressure: ____ / ____ mmHg
<b>BldPrDia</b>	
<b>PregTestDt</b>	4. Date of negative urine pregnancy test: ____ / ____ / ____ mm/dd/yy (If
<b>PregTestNotDoneMF</b>	not done indicate reason below)
	4a. If not done, why: <i>Dropdown list (Subject is Male, Premenstrual, Surgically sterile, Other)</i>
	4aii. If reason is 'Other,' please describe: _____
<b>AbnPresent</b>	5. Were there any abnormalities present on the physical exam that are pertinent to the study? <input type="checkbox"/> Yes <input type="checkbox"/> No
	5a. If yes, please describe: _____

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**Medical History**

<b>PreExistMedCond</b> 1. Does the subject have any pre-existing medical conditions other than T1DM? <input type="checkbox"/> Yes <input type="checkbox"/> No (If yes, please complete the Medical Conditions form online)
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**Concomitant Medications**

<b>ConComMed</b> 1. Is the subject currently taking any medication other than insulin? <input type="checkbox"/> Yes <input type="checkbox"/> No (If yes, please complete the Concomitant Medications form online)
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