Open Loop End Visit

Visit Information Section

tblOpenLoopEnd

1. Name of Investigator _____

VisitDt

2. Visit Date: _____

Open Loop End Section

Eligibility Assessment

DiAsStatus	1. **Did the subject successfully use the DiAs system in open-loop mode at home 80% of the time so he/she is eligible to continue in the study?**
	☐**Yes**
	☐**No, 1-week of open-loop system use at home to be repeated** *(Please comment below)*
	☐**No, subject will be discontinued from study** *(Please comment below and submit a Final Status form)*
	If No, please describe why:
	_____ _____ _____ _____

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)**
SevHyper	**Did the subject have a DKA not already reported?** ☐Yes ☐No **(If Yes, complete an Adverse Event Form)** **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 occurred that has not already been reported?** ☐Yes ☐No **(If Yes, complete an Adverse Event Form)**
AdverseEvent	