TASK DOCUMENTATION
[AEs and Device Problems]

Participant ID: PtID

	ADVERSE EVENTS
	1. Did any of the following occur since last visit?
SHSinceLastVis	**a. Reportable Hypoglycemic event*:** O Yes O No ***If Yes, complete AE form and Hypoglycemic Event form.*** ***Reportable hypoglycemia*** *is defined as an event that required assistance of another person due to altered consciousness to actively administer carbohydrate, glucagon, or other resuscitative actions. This means that the participant was impaired cognitively to the point that the participant was unable to treat his or herself, was unable to verbalize his or her needs, was incoherent, disoriented, and/or combative, or experienced seizure or coma. By definition, events that meet these criteria are reported as Serious Adverse Events. Hypoglycemic events are also considered reportable if the above criteria are not met but emergency evaluation or treatment was obtained from a health care provider; these events are considered Adverse Events and not Serious Adverse Events unless one of the criteria for SAE is met.* **b. Definite or Probable DKA*:** O Yes O No ***If Yes, complete AE form and DKA form.***
DKASinceLastVis	***Definite Diabetic Ketoacidosis*** *(as defined by the DCCT) is defined as having all of the following:* *(1) Symptoms such as polyuria, polydipsia, nausea, or vomiting* *(2) Serum ketones >1.5 mmol/L or large/moderate urine ketones* *(3) Either arterial blood pH <7.30 or venous pH <7.24 or serum bicarbonate <15* *(4) Treatment provided in a health care facility* *By definition, definite DKA is reported as a Serious Adverse Event.* ***Probable Diabetic Ketoacidosis*** *means in the judgment of the investigator the participant had DKA but not enough information is available to categorize event as meeting the above criteria; these events are considered Adverse Events, and not Serious Adverse events unless one of the criteria for SAE is met.*
OthAESinceLastVis	**c. Other reportable adverse event*:** O Yes O No ***If Yes, complete AE form.*** ***Reportable Adverse Event—****(1)* severe hypoglycemia as defined above, (2) diabetic ketoacidosis as defined above, (3) all device-related events, and (4) all events meeting criteria for a serious adverse event. Skin reactions from sensor placement are only reportable if severe and/or required treatment. Hyperglycemia that does not meet criteria for definite or probable DKA is reported as an Adverse Event if emergency evaluation or treatment was obtained from a health care provider.

	DEVICE PROBLEMS
DevProbSinceLastVis	**1. Did the participant report having any reportable device problems while using a study device since the last contact?** O Yes O No **If Yes, complete the Device Issue Form.**