

## Open-Loop Transitional Training Visit

### tblOpenLoopTraining

#### Identifying Information

PtID

1. Patient ID: CTR3-\_\_\_\_ - \_\_\_\_\_
2. Initials: \_\_\_\_\_

#### Visit Information

VisitDt

1. Visit Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_ mm/dd/yy
2. Study ID of Investigator: \_\_\_\_ - \_\_\_\_\_

#### Urine Testing *(Only required if female)*

PregTestDt

PregTestNotDoneMF

1. If subject is female,
  - a. Date of negative urine pregnancy test: \_\_\_\_ / \_\_\_\_ / \_\_\_\_ mm/dd/yy (If not done indicate reason below)
    - ai. If not done, why: *Dropdown list (Premenstrual, Surgically sterile, Male, Other)*
    - aii. If reason is 'Other,' please describe:  
\_\_\_\_\_  
\_\_\_\_\_

#### Open-Loop Supplies

TranslatorBoxNotUsed

DexcomReceiverNotUsed

1. DiAs Serial Number: \_\_\_\_\_
2. Translator Box Serial Number: \_\_\_\_\_  
☐ N/A, no translator box used
3. Dexcom Receiver Serial Number: \_\_\_\_\_  
☐ N/A, no receiver used

	<b>4. Dexcom Transmitter Serial Number:</b> _____
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**Open-Loop Training and Assessment** [SubEligibility](#)

Were the following training and assessment steps completed successfully and in the opinion of the investigator, are the subject and companion ready for open-loop use of the system at home? ☐Yes ☐No

- ☐ Pump parameters entered in the study system were confirmed by the study investigator.
- ☐ Subject and companion able to connect CGM and pump to DiAs.
- ☐ Subject and companion able to switch the system between its operational modes (Pump (Open-Loop), Stopped mode, etc.) appropriately.
- ☐ Subject and companion able to calibrate the CGM.
- ☐ Subject and companion able to access and interpret the CGM trace using the DiAs system.
- ☐ Subject and companion able to administer insulin with a meal and give correction insulin as needed using the DiAs.
- ☐ Subject and companion able to inform the DiAs system of a hypoglycemia treatment and understands the system must be informed after each ~16 grams of glucose is consumed.
- ☐ Subject participated in a period of light exercise, and subject and companion understand how to use the system when the subject will be exercising.
- ☐ Subject and companion able to perform ketone testing and use glucagon kit for rescue therapy
- ☐ Subject and companion demonstrate clear understanding of the DiAs system interface and how to react to safety/alert messages.
- ☐ The subject and companion were provided a printed User Guide as a reference.