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DAFNE number /
Participant Initials



REPOSE STUDY

On-going Data Collection Booklet

This booklet contains the severe hypo log, adverse event / reaction log and diabetes related contact log

- 1) At Baseline, please record a 12 month history of severe hypos.**
- 2) At the 6, 12 and 24 month visits please ensure that the severe hypo, adverse event / reaction and diabetes related contact logs are up to date.** (This may involve transposing any loose severe hypo, adverse event / reaction and contact forms onto their respective logs).

Beware of double counting events



Severe Hypo Log

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Severe Hypoglycaemic Episodes – Severe hypoglycaemia is defined as an episode leading to cognitive impairment (confusion or inability to think straight) sufficient to either cause coma or requiring the assistance of another person to recover.

#	Date reported	Occurred prior to Baseline (✓)	Description of Hypo		Did family/friend administer Glucagon? (Y/N)**	Required paramedic assistance (Y/N)	A&E attendance (Y/N)	Hospitalisation (Y/N)***	Unconsciousness (Y/N)	Lowest Blood Glucose at time of severe hypo (mmol/L)	Measured before or after treatment?	Confirmed by educator as Severe hypo	
			Date <small>(if day is not known, please provide month and year)</small>	Reason*								(✓)	Educator initials
1	<input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input style="width: 20px; height: 20px;" type="text"/>							<input style="width: 20px; height: 20px;" type="text"/>		<input type="checkbox"/>	
2	<input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input style="width: 20px; height: 20px;" type="text"/>							<input style="width: 20px; height: 20px;" type="text"/>		<input type="checkbox"/>	
3	<input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input style="width: 20px; height: 20px;" type="text"/>							<input style="width: 20px; height: 20px;" type="text"/>		<input type="checkbox"/>	
4	<input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input style="width: 20px; height: 20px;" type="text"/>							<input style="width: 20px; height: 20px;" type="text"/>		<input type="checkbox"/>	
5	<input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input style="width: 20px; height: 20px;" type="text"/>							<input style="width: 20px; height: 20px;" type="text"/>		<input type="checkbox"/>	
6	<input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input style="width: 20px; height: 20px;" type="text"/>							<input style="width: 20px; height: 20px;" type="text"/>		<input type="checkbox"/>	
7	<input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input style="width: 20px; height: 20px;" type="text"/>							<input style="width: 20px; height: 20px;" type="text"/>		<input type="checkbox"/>	
8	<input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input style="width: 20px; height: 20px;" type="text"/>							<input style="width: 20px; height: 20px;" type="text"/>		<input type="checkbox"/>	
9	<input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input style="width: 20px; height: 20px;" type="text"/>							<input style="width: 20px; height: 20px;" type="text"/>		<input type="checkbox"/>	
10	<input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input style="width: 20px; height: 20px;" type="text"/>							<input style="width: 20px; height: 20px;" type="text"/>		<input type="checkbox"/>	

*No food, illness, exercise, alcohol , other (please specify)

** **Confirm** family/friend assistance was required for recovery (if the participant could have administered glucagon themselves if no one was around this is not a severe hypo)

*** If the participant was hospitalised this hypo **must** be reported as a serious adverse event using the SAE form within four weeks of finding out about it.



Adverse Event / Reaction Log

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#	Category* Choose from below	Start date	Ongoing (✓)	End date	Related to study drug	Serious** See right for how to asses if AE serious
1		<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
2		<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
3		<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
4		<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
5		<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
6		<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
7		<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
8		<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
9		<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
10		<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

****Assessing Severity**
 Rated as serious if meets any of the following criteria:

- results in death;
- is life-threatening^A (subject at immediate risk of death)
- requires in-patient hospitalisation or prolongation of existing hospitalisation^B
- results in persistent or significant disability or incapacity, or consists of a congenital anomaly or birth defect
- is another important medical event that may jeopardise the subject^C

^A "life-threatening" in the definition of "serious" refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

^B Hospitalisation is defined as an inpatient admission, regardless of length of stay, even if the hospitalisation is a precautionary measure for continued observation. Hospitalisations for a pre-existing condition, including elective procedures that have not worsened, do not constitute an SAE.

^C Other important medical events that may not result in death, be life-threatening, or require hospitalisation may be considered a serious adverse event/experience when, based upon appropriate medical judgement, they may jeopardise the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

***Category**

- 1 = An increase in frequency of hypoglycaemia that is suddenly noticeable to the patient/patient's relatives;
- 2 = Blood glucose reading >30 mmol/L;
- 3 = Unexplained constantly raised blood glucose readings (defined as three consecutive readings > 20mmol over 12 hours);
- 4 =Suspicion of pump malfunction (adjudicated by the educator). Note: Medtronic must be notified via their technical helpline;
- 5 = Pregnancy (so that any ARs may be identified if and when the child is born);
- 6 = Infection at pump cannula site / pump site infection
- 7 = Other, please specify

All serious adverse events or reactions must also be reported using the SAE form



Diabetes related contact log

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#	Contact date and time (24 hour)	Contact type	Duration of contact (to the nearest 5 mins)	Notes
1	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/> Telephone <input type="checkbox"/> Face to face / clinic <input type="checkbox"/> Email	<input type="text"/> hours <input type="text"/> mins	
2	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/> Telephone <input type="checkbox"/> Face to face / clinic <input type="checkbox"/> Email	<input type="text"/> hours <input type="text"/> mins	
3	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/> Telephone <input type="checkbox"/> Face to face / clinic <input type="checkbox"/> Email	<input type="text"/> hours <input type="text"/> mins	
4	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/> Telephone <input type="checkbox"/> Face to face / clinic <input type="checkbox"/> Email	<input type="text"/> hours <input type="text"/> mins	
5	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/> Telephone <input type="checkbox"/> Face to face / clinic <input type="checkbox"/> Email	<input type="text"/> hours <input type="text"/> mins	
6	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/> Telephone <input type="checkbox"/> Face to face / clinic <input type="checkbox"/> Email	<input type="text"/> hours <input type="text"/> mins	
7	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/> Telephone <input type="checkbox"/> Face to face / clinic <input type="checkbox"/> Email	<input type="text"/> hours <input type="text"/> mins	
8	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/> Telephone <input type="checkbox"/> Face to face / clinic <input type="checkbox"/> Email	<input type="text"/> hours <input type="text"/> mins	
9	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/> Telephone <input type="checkbox"/> Face to face / clinic <input type="checkbox"/> Email	<input type="text"/> hours <input type="text"/> mins	
10	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/> Telephone <input type="checkbox"/> Face to face / clinic <input type="checkbox"/> Email	<input type="text"/> hours <input type="text"/> mins	
11	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/> Telephone <input type="checkbox"/> Face to face / clinic <input type="checkbox"/> Email	<input type="text"/> hours <input type="text"/> mins	
12	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/> Telephone <input type="checkbox"/> Face to face / clinic <input type="checkbox"/> Email	<input type="text"/> hours <input type="text"/> mins	
13	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/> Telephone <input type="checkbox"/> Face to face / clinic <input type="checkbox"/> Email	<input type="text"/> hours <input type="text"/> mins	
14	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/> Telephone <input type="checkbox"/> Face to face / clinic <input type="checkbox"/> Email	<input type="text"/> hours <input type="text"/> mins	
15	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/> Telephone <input type="checkbox"/> Face to face / clinic <input type="checkbox"/> Email	<input type="text"/> hours <input type="text"/> mins	