FOR OFFICE USE ONLY

DAFNE number /

Participant Initials

REPOSE STUDY

Data Collection Booklet

24 month

04/02/2014 v1

re/sose 24 month Data Collection

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DAFNE number ___ ___ ___ / ___ ___ ___ ___

Participant Initials ___ ___ ___

Please find below the checklist for the 24 month data collection visit. Please read the checklist carefully and ensure that all of the items have been addressed by the end of the visit.

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Checklist for 24 month data collection visit:

- ☐ Taken blood and urine samples
- ☐ **Updated on-going data collection booklet - checked that all severe hypos, contacts and AEs have been recorded; where applicable end dates for AEs should also be provided (may need to check patient notes)**
- ☐ Checked for any unreported SAEs (check patient notes)
- ☐ Collected the psychosocial questionnaire. If the participant has not brought it to the appointment ask them to fill in a questionnaire now
  (They may also hand you a 'permission for future contact' slip. If so please return to CTRU; please send in a separate envelope to the questionnaires)
- ☐ Downloaded previous week data from Bolus calculator
- ☐ Completed the 'Study Completion / Discontinuation' form
  (If the participant has attended their 24m follow-up visit they have completed the study)

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Date of data completion d d m m y y y y

Where do you receive your diabetes care? ☐ GP only ☐ Specialist care

Test	Date specimen taken	Result
HbAlc (central lab)	d d m m y y y y	mmol/mol
HbAlc (local lab) specify lab	d d m m y y y y	mmol/mol
Creatinine	d d m m y y y y	. µmol/L
Albumin-creatinine	d d m m y y y y	. mg/mmol OR ☐ < 2 OR ☐ < 3 OR < ☐ OR ☐ Unable to calculate
Cholesterol	d d m m y y y y	. mmol/L
Triglycerides	d d m m y y y y	. mmol/L
HDL cholesterol	d d m m y y y y	. mmol/L
eGFR	d d m m y y y y	mls/min/1.73m² OR ☐ >60 mls/min/1.73m2 ☐ >90 mls/min/1.73m2 OR other ☐

Date of last full annual review d d m m y y y y

Date of last retinal screening (including retinal photography) d d m m y y y y

Weight . kg

Height . cm

Blood pressure /

Systolic Diastolic

Physical activity

- ☐ High (equivalent to more than 8 hours normal walking, 4 hours fast walking or 2.5 hours running per week)
- ☐ Medium (equivalent to between 4 and 8 hours normal walking, 2 and 4 hours fast walking or 1.25 and 2.5 hours running per week)
- ☐ Low (equivalent to less than 4 hours normal walking, 2 hours fast walking or 1.25 hours running per week)

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Participant Initials ☐☐☐

Are you currently using an insulin pump? ☐ Yes ☐ No

Date that you started to use the insulin pump d d m m y y y y

Treatment details

Please record details about the MDI / Pump treatment (e.g. any temporary breaks from allocated treatment), including dates and reasons where applicable. For example: Break from Pump 12/03/2012-15/03/2012, patient on holiday

MDI only

Current MDI insulin regimen (REPOSE ratios of Quick Acting (QA): Carbohydrate Portion (CP) and Background Insulin (BI) doses, use previous day's doses):

Current MDI insulin regimen	**Typical daily dose** (based on use in the last week and using diary entries/expert meters)	**Number of injections per day**
Quick acting (QA)	☐☐ i.u.	☐☐
Background insulin (BI)	☐☐☐ i.u.	☐
Pre-mixed insulin (Mix)	☐☐☐ i.u.	☐

Is the participant using ratios? ☐ Yes ☐ No

QA:CP Ratios: ☐.☐☐:1b ☐.☐☐:1m ☐.☐☐:1e ☐.☐☐:1s

Pump users only

Current pump regimen (REPOSE ratios of Insulin: Carbohydrate and Basal Insulin (BI) regime, use previous day's doses):

(All questions relating to dose should be calculated based on use in the last week and using diary entries/expert meters)

Typical/usual daily bolus total: ☐☐☐.☐ i.u.
(**Note**: whole number NOT range)

24 hour basal dose: ☐☐☐.☐☐☐ i.u.

Average number of boluses per day (based upon 'usual' day) ☐☐

Is the participant using ratios? ☐ Yes ☐ No

QA:CP Ratios: ☐.☐☐:1b ☐.☐☐:1m ☐.☐☐:1e ☐.☐☐:1s

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Insulin type

QA: ☐ Human ☐ Animal ☐ Novo Rapid ☐ Humalog ☐ Apidra

Method of delivery : ☐ Syringe ☐ Reusable pen ☐ Disposable pen ☐ Pump

BI: ☐ Human ☐ Animal ☐ Lantus ☐ Levemir

Method of delivery: ☐ Syringe ☐ Reusable pen ☐ Disposable pen

Mix: ☐ Human ☐ Animal ☐ Analogue

Method of delivery : ☐ Syringe ☐ Reusable pen ☐ Disposable pen

Appearance of injection sites - is Lipohypertrophy present? ☐ Yes ☐ No

Medication

Lipid lowering (Statin; Fibrate; Ezetimibe) ☐ Yes ☐ No

Antiplatelet agent (Aspirin; Clopidrogel; Dipyridamole) ☐ Yes ☐ No

Medication for depression (exclude antidepressants for neuropathy) ☐ Yes ☐ No

Have you been pregnant since your last REPOSE visit? ☐ Yes ☐ No

Are you pregnant now? ☐ Yes ☐ No

Current gestation (weeks) ☐☐

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Moderate Hypoglycaemic Episodes (to be completed by educator with patient)

Moderate hypoglycaemia is defined as **any** episode which could be treated by that individual, but where hypoglycaemia caused significant interruption of current activity, such as having caused impaired performance or embarrassment or having been woken during sleep.

They do not necessarily need to be confirmed by a blood glucose measurement although the person should be confident that their symptoms were due to hypoglycaemia.

How many moderate hypoglycaemic episodes have you had during the last 4 weeks? (use BG diary entries)

Please give details of moderate hypos, where known, in the log below:
(use continuation sheet on page 11 for additional records)

Approximate date	Reason for Hypo (i.e no food, exercise, illness, alcohol etc)	Woken from sleep (Y/N)	Blood Glucose Level (mmol/L)	Measured before or after treatment	Confirmed by educator as moderate hypo*	
					(✓)	Educator initials
d d m m y y y y			.			
d d m m y y y y			.			
d d m m y y y y			.			
d d m m y y y y			.			
d d m m y y y y			.			
d d m m y y y y			.			
d d m m y y y y			.			
d d m m y y y y			.			
d d m m y y y y			.			
d d m m y y y y			.			
d d m m y y y y			.			
d d m m y y y y			.			
d d m m y y y y			.			
d d m m y y y y			.			
d d m m y y y y			.			

* Educator must be certain that the patient was able to treat the episode of hypoglycaemia themselves.

24 month Data Collection

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Participant Initials ___ ___ ___

Severe hypoglycaemic episodes We will use a standard definition of severe episodes: an episode leading to cognitive impairment (confusion or inability to think straight) that is either sufficient to cause a coma or requires the assistance of another person to recover.

Has participant had any severe hypos since the last **REPOSE** visit? ☐ Yes ☐ No

Adverse Events Have any of the following occurred?

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

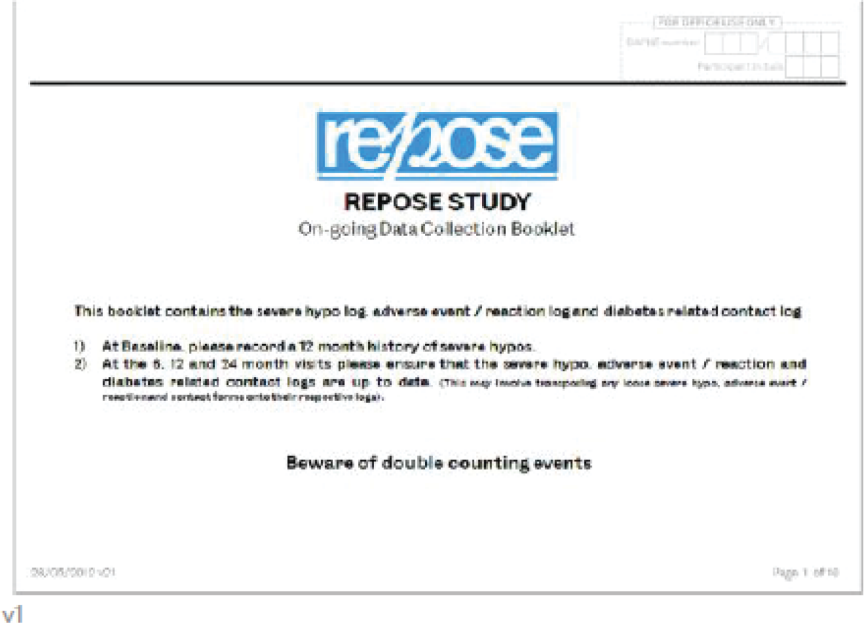
Has participant had any adverse events since the last **REPOSE** visit? ☐ Yes ☐ No

Phone / clinic contacts Have contacts occurred since the last **REPOSE** visit?

Has there been any contacts since the last **REPOSE** visit? ☐ Yes ☐ No

If yes to any of the above, please check that these events have been reported and are in the on-going data collection booklet

Please also review all on-going Adverse Events and where applicable enter the end date



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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

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Complications (conditions and events) since the last **REPOSE** visit? ☐ Yes ☐ No

If yes, please record below which conditions are present and the date of onset for each:

Condition (tick if present)	**Date of onset**
☐ Hypertension	d d m m y y y y
☐ Painful neuropathy	d d m m y y y y
☐ Foot ulcer	d d m m y y y y
☐ Retinopathy	d d m m y y y y
☐ Proliferative	d d m m y y y y
☐ Registered partially sighted	d d m m y y y y
☐ Registered blind	d d m m y y y y
☐ Microalbuminuria (Female = greater than 3.5 on 2 occasions, at least 1 early morning urine) (Male = greater than 2.5 on 2 occasions, at least 1 early morning urine)	d d m m y y y y
☐ Proteinuria (Dipstick positive and/or ACR greater than 30 on 2 occasions and/or greater than 300mg/l in 24 hours)	d d m m y y y y
☐ Erectile dysfunction	d d m m y y y y

If yes, please record below which of the events have happened and the date of the most recent occurrence for each.

Event (tick if present)	**Date of event**
☐ MI	d d m m y y y y
☐ Heart failure	d d m m y y y y
☐ Coronary revascularisation	d d m m y y y y
☐ Peripheral revascularisation	d d m m y y y y
☐ CVA	d d m m y y y y
☐ Amputated toe	d d m m y y y y
☐ Amputation above toe level	d d m m y y y y
☐ Laser Rx	d d m m y y y y
☐ Dialysis	d d m m y y y y
☐ Renal transplantation	d d m m y y y y

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Total number of **diabetes related** inpatient episodes since the last **REPOSE** visit ___

Bolus calculator

How often does the patient use their bolus advisor/calculator for the following functions:

	Never	Rarely (about 25% of the time)	Sometimes (about 50% of the time)	Often (about 75% of the time)	Always
Calculation of insulin dosage					
Calculation of correction doses					
Any other activities (e.g. exercise, menstruation)					

Where the bolus calculator advisor is used for the calculation of insulin boluses for food, how frequently is the advice given used?

Never	Rarely (about 25% of the time)	Sometimes (about 50% of the time)	Often (about 75% of the time)	Always

Previous one week download data collected from bolus calculator ☐ Yes ☐ No

How many admissions due to Diabetic Ketoacidosis (DKA) have you had in total?

Total number ever ___

Total number since the last **REPOSE** visit ___

Number of telephone contacts regarding your diabetes with **any** healthcare professional since the last **REPOSE** visit ___

Number of face to face/clinic contacts regarding your diabetes with **any** healthcare professional since the last **REPOSE** visit ___
(exclude any inpatient hospital admissions)

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Please note the number of blood tests...

performed in the last 2 weeks ☐☐

recorded (e.g. written down) in the last 2 weeks ☐☐

Do your symptoms of hypogylcaemia usually occur at a blood glucose level of:

- ☐ Greater than/equal to 3mmol/l
- ☐ Less than 3mmol/l
- ☐ Do not feel symptoms

Please record the method of data collection (more than one can be selected where necessary):

- ☐ Face to face
- ☐ Telephone
- ☐ Hospital records

Data collected by (Print name) _____ Signature _____

This is the end of the 24 month data collection booklet. Please now ensure that the checklist items on page 2 have been addressed.

re/pose 24 month
Data Collection

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Moderate Hypoglycaemic Episodes (continuation sheet)

Please give details of moderate hypos, where known, in the log below:

Approximate date	Reason for Hypo (i.e no food, exercise, illness, alcohol etc)	Woken from sleep (Y/N)	Blood Glucose Level (mmol/L)	Measured before or after treatment	Confirmed by educator as moderate hypo*	
					(✓)	Educator Initials
d d m m y y y y			.		☐	
d d m m y y y y			.		☐	
d d m m y y y y			.		☐	
d d m m y y y y			.		☐	
d d m m y y y y			.		☐	
d d m m y y y y			.		☐	
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d d m m y y y y			.		☐	

* Educator must be certain that the patient was able to treat the episode of hypoglycaemia themselves.

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Additional notes

Please use this section to make any additional notes (e.g. expansion on checklist items)