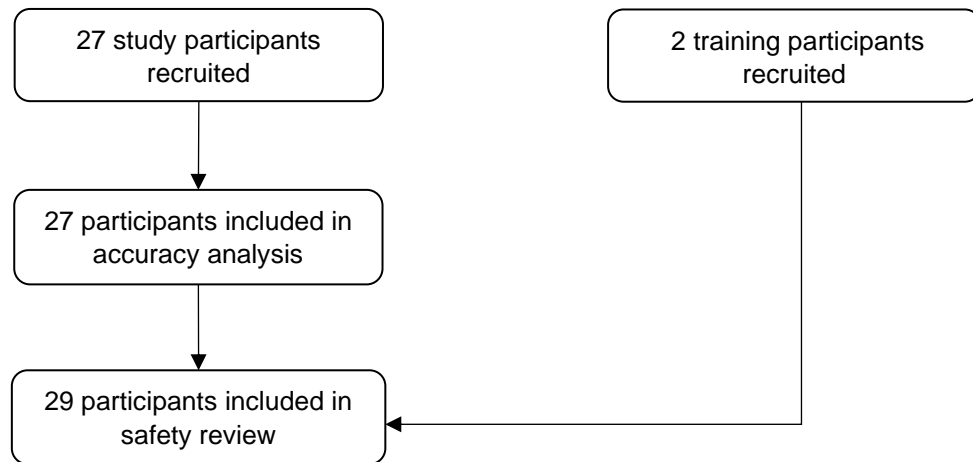


## **ISRCTN64992339: FreeStyle Libre potential in-reader correction study**

### **1. Study Flow**



**Figure 1** Study flow diagram

### **2. Baseline characteristics**

Variable	Baseline
Mean age $\pm$ SD (years)	49.6 $\pm$ 13.8
Sex, male	17 (63.0%)
Diabetes	
Type 1	15 (55.6%)
Type 2	12 (44.4%)
Mean HbA1c $\pm$ SD (%)	9.1 $\pm$ 2.0

**Table 1** Baseline characteristics of study population (n=27)

### **3. Outcome measures**

The system accuracy measured using percentage of readings that are within  $\pm 20\%$  of the YSI reference value for glucose levels  $\geq 80$  mg/dL (4.4 mmol/L) and within  $\pm 20$  mg/dL (1.1 mmol/L) for YSI glucose levels  $< 80$  mg/dL (4.4 mmol/L), with and without in-reader correction are shown (Table 2). A total of 53 sensors were included in the accuracy analysis.

% Within YSI Reference	In reader correction	
	No	Yes
Within $\pm 20\%$ / 20 mg/dL	3212 / 3861 (83.2%)	3342 / 3861 (86.6%)

**Table 2:** System accuracy compared to YSI reference

### **4. Adverse events**

Adverse event	Number of patients affected	Number of events
Serious adverse events	0	0
Other (not including serious) adverse events	7 (24.1%)	9
Device related (anticipated)		
Pain	1 (3.4%)	1
Bruising	1 (3.4%)	1
Bleeding	1 (3.4%)	1
Erythema	1 (3.4%)	1
Study procedure related		
Cannula site events	2 (6.9%)	2
Hypoglycaemia	3 (10.3%)	3

**Table 3:** Summary of adverse events recorded (n=29)