

# User Evaluation of the DexCom™ SEVEN.2 Continuous Glucose Monitoring System

<b>Submission date</b> 19/05/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 29/06/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 29/06/2009	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Thomas Danne

**Contact details**  
Janusz-Korczak-Allee 12  
Hannover  
Germany  
30173

## Additional identifiers

**Protocol serial number**  
Protocol Nr. 5181

## Study information

**Scientific Title**  
User Evaluation of the DexCom™ SEVEN.2 Continuous Glucose Monitoring System: a single-centre prospective non-randomised masked/un-masked intervention study

**Study objectives**  
The study intends to evaluate user experience with the DexCom™ SEVEN.2 Continuous Glucose Monitoring System in the home environment and the effect of its use on glycaemic control.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics Committee of Hannover Medical School approved on the 28th November 2008

**Study design**

Single-centre prospective non-randomised masked/un-masked intervention study

**Primary study design**

Interventional

**Study type(s)**

Quality of life

**Health condition(s) or problem(s) studied**

Type 1 diabetes mellitus

**Interventions**

During baseline Phase 1 (duration 21 days), subjects will be masked to the display of the DexCom™ SEVEN.2 continuous glucose readings. Subjects will calibrate the DexCom™ SEVEN.2 Receiver using standard fingerstick blood glucose testing with test strips. Subjects will manage their diabetes based upon the blood glucose measurements using their established regimen prescribed by their healthcare professional prior to study enrolment.

At the end of the Phase 1, subjects will return to the clinic to have their DexCom™ SEVEN.2 systems set to display continuous glucose readings and enable low and high glucose alarms. Subjects will continue for the rest of the study using the DexCom™ SEVEN.2 system as an adjunctive device to guide glucose management according to its intended use and warnings given in the User's Guide along with the advice of the study Investigator.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

To evaluate improvement in glycaemic variability in children, adolescents, and young adults, particularly in the reduction of the number of hypo- and hyper-glycaemic events, reduction of time spent outside of euglycemia glucose range, and reduction of glucose variability (standard deviation) through use of the DexCom™ SEVEN.2 Continuous Glucose Monitoring System, between masked and un-masked period.

**Key secondary outcome(s))**

To evaluate user experience with the DexCom™ SEVEN.2 Continuous Glucose Monitoring System. The HbA1C level will also be evaluated; the unmasked baseline phase A1C will serve as a self-control for the subjects.

**Completion date**

15/04/2009

## Eligibility

### Key inclusion criteria

1. Documented type 1 diabetes mellitus diagnosis at least 1 year prior to enrolment
2. Recommended to perform daily self-monitoring blood glucose testing
3. Performing multiple daily insulin injections, or has been on an insulin pump, for at least 6 months prior to enrolment
4. Less than 24 years of age, either sex
5. Willing and capable of following the protocol and instructions provided by the investigator
6. Available for the entire study duration of 63 days and for follow up on scheduled study visit days
7. Provided written informed consent

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Sex

All

### Key exclusion criteria

1. Subject has had an episode of severe hypoglycaemia in past four weeks prior to enrolment
2. Allergy to medical grade adhesives
3. Any medical condition or medication, which in the investigators opinion, may compromise patient safety
4. Participation in any other study which may affect glucose measurements or glucose management
5. Known, suspected or planning pregnancy during study participation

### Date of first enrolment

15/12/2008

### Date of final enrolment

15/04/2009

## Locations

### Countries of recruitment

Germany

### Study participating centre

**Janusz-Korczak-Allee 12**  
Hannover  
Germany  
30173

## **Sponsor information**

### **Organisation**

DexCom Inc. (USA)

### **ROR**

<https://ror.org/03ra42c27>

## **Funder(s)**

### **Funder type**

Industry

### **Funder Name**

DexCom Inc. (USA)

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration