

# Ease of Use and Comfort of a Novel Sensor Insertion Device for Continuous Glucose Monitoring

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**Background:** In continuous glucose monitoring (CGM) the accurate positioning of the sensor in the subcutaneous tissue is a pre-requisite for adequate sensor performance. In this study



Figure 1: CGM system components: transmitter, sensor base, sensor inserter (from left to right).

a novel sensor inserter was investigated with regard to success and reliability of sensor insertion, ease-of-use of the device, and the level of discomfort associated with the insertion procedure.

**Subjects:** 50 adult subjects with diabetes mellitus type 1 or type 2 on insulin therapy, recruited from inpatients at the

Diabetes Zentrum Mergentheim, participated in the study. 34 subjects had no prior experience with CGM systems.

**Test Procedure:** After some instructions and familiarization with the insertion procedure, the study participants inserted themselves sensors into the subcutaneous tissue of the abdomen and/or the subcutaneous tissue of the hip/buttock. For each completed insertion process, a reading of the penetration length of the sensor was taken and the insertion site with the scaling sensor was documented by photo recording using a high-resolution micro camera. The sensors were removed after photo documentation. In addition, observations regarding usability and pain were recorded.

**Evaluation of insertion success and pain sensation during sensor insertion:** To determine the insertion length, a sensor with a special scale was used (see Fig. 2). Sensors were seen as being inserted successfully if the insertion length was  $\geq 8$  mm.

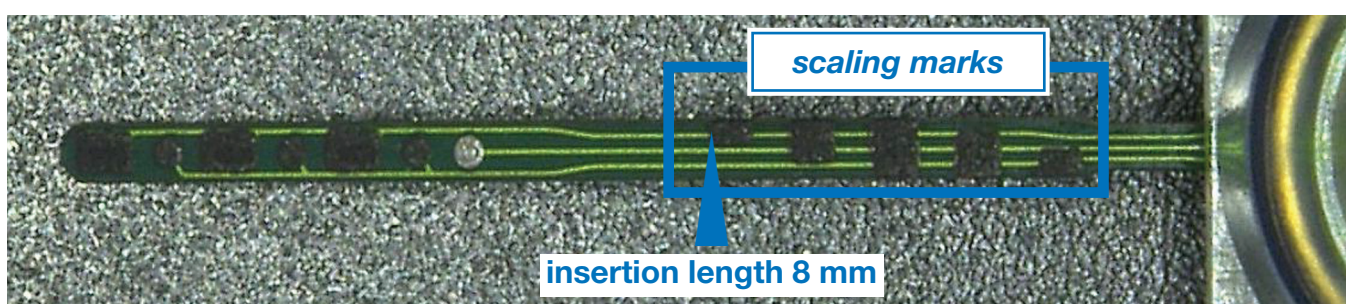


Figure 2: Sensor with scaling marks

Pain sensation associated with the insertion process was determined by qualitative assessment and compared to the pain sensation associated with the insertion of other CGM sensors, the injection of insulin, or capillary blood sampling for BG measurement.

For the qualitative assessment of pain a visual analogue scale (VAS) was used. The marks on the analogue scale were assigned to 3 categories: “low”, “moderate”, and “high” (see Fig. 3).

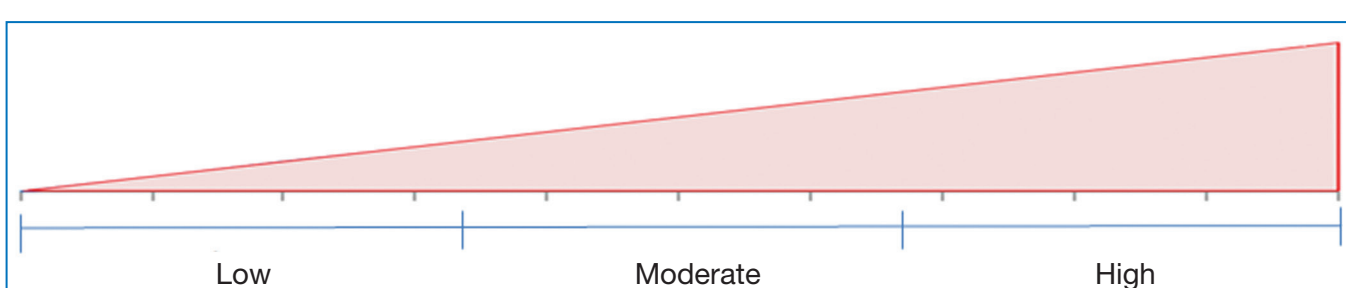


Figure 3: Visual analogue scale (VAS) for assessment of pain

**Results:** Overall, 74 insertion experiments were performed. Three insertions were excluded from the calculation of the insertion success rate due to protocol deviation or equipment failure.

The remaining 71 sensors were inserted successfully with an insertion length  $\geq 8$  mm, leading to a success rate of sensor insertion of 100 %.

Pain upon sensor insertion was reported to be low (77.5 %) or moderate (18.3 %). There were no substantial differences in pain sensation between the three insertion sites (see Table 1).

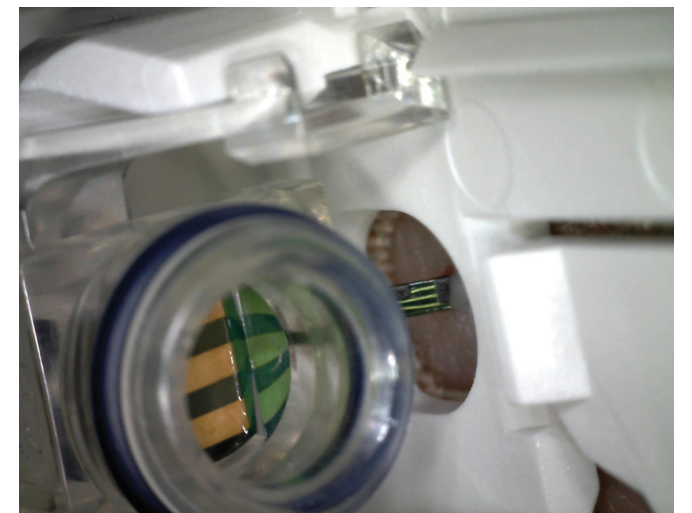


Figure 4: Sensor with scaling marks inserted successfully into the subcutaneous tissue

Pain sensation during insertion process	Insertion Site			Total
	Abdomen, right hand site	Abdomen, left hand site	Hip/buttock, right- or left-hand site	
Low	18	20	17	55 (77.5 %)
Moderate	4	5	4	12 (18.3 %)
High	1	0	2	2 (4.2 %)

Table 1: Pain sensation during the insertion process

(N = 71 insertion experiments; assessment directly subsequent to insertion)

Compared to other measures in the treatment of diabetes, the level of discomfort experienced with insertion using the novel sensor inserter was reported to be equal to or less than discomfort experienced with finger pricking (79.6 %), insulin injection (77.6 %) or applying other CGM systems (83.3 %).

At the end of the test, the participants were asked for their overall assessment of the system. Regarding the handling of the insertion device, 80 % of the subjects rated it as very easy to use, and 98 % rated the operating steps as easy to understand. Table 2 shows the usability flash results.

Statement	Mean Rating
Overall impression of the handling of the system	2.2
The system appeals safe and reliable	2.0
Operating procedure was easy to understand	1.4
Inserter was easy to hold / easy to grip	1.9
Operating elements were easy to understand	1.6
Operating elements were easy to reach and easy to grip	1.8
Operational effort was little	2.2
Overall easy to handle	1.9

Table 2: Usability flash results. Statements were rated on a scale ranging from 1 (= best rating) to 6 (= worst rating)

## Summary:

- All sensors were inserted successfully into the subcutaneous tissue of the abdomen and/or the hip/buttock.
- The sensor base and sensor inserter were easy to operate, and the procedure was easy to learn and understand.
- Pain sensation associated with the insertion process was rated as low to moderate.
- The majority of subjects evaluated the pain associated with the insertion as equivalent to or less painful than in other similar procedures related to diabetes management.

**Conclusion:** The novel CGM sensor inserter can provide people with diabetes with a reliable and easy-to-use procedure for safe and successful sensor insertion with a minimum of discomfort, also when compared to other CGM devices and other measures in the treatment of diabetes.