

## The Hypo-Safe device

Hypoglycemia is feared by all insulin-treated diabetics due to the dramatic short term effects including inability to concentrate, seizure, unconsciousness, permanent brain damage or even death. The fear of hypoglycemia is considered to be the major obstacle to achieving a good glycaemic control. In the USA and Europe approximately 25% of all diabetics use insulin to control their glucose levels corresponding to approximately 6 million insulin-treated in the USA and 7 million in Europe. Unawareness, defined as a reduced or abolished ability to sense and respond to hypoglycemia, is a predictor for the risk of severe hypoglycemia. 25% of the insulin treated diabetic patients are suffering from “unawareness” – resulting in thousands of hospitalizations daily.

During hypoglycemia, the brain metabolism is impaired (neuroglycopenia) resulting in significant and characteristic changes of the electroencephalogram (EEG). By utilizing the brain as a bio-sensor the Hypo-Safe device records and computes the electrical patterns of the EEG. Prior to a hypoglycemic event these characteristic patterns are detected and thus allows for the patient to react in timely manner. The Hypo-Safe device is the world’s first EEG monitoring device for diabetics unable to feel and respond to a critical low blood sugar level. By warning the carrier before a critically low blood sugar level is reached in the brain, the device prevents hypoglycemia with potential fatal consequences.

Traditionally EEG is monitored either by surface electrodes (widely used) or by sub cranial implanted electrodes (for diagnostics only). The Hypo-Safe device uses a subcutaneous electrode, providing an accurate recording with negligible artifacts from loose wires, patient movements, sweating as seen with surface electrodes. The implantation procedure is harmless and takes approx 15 minutes.

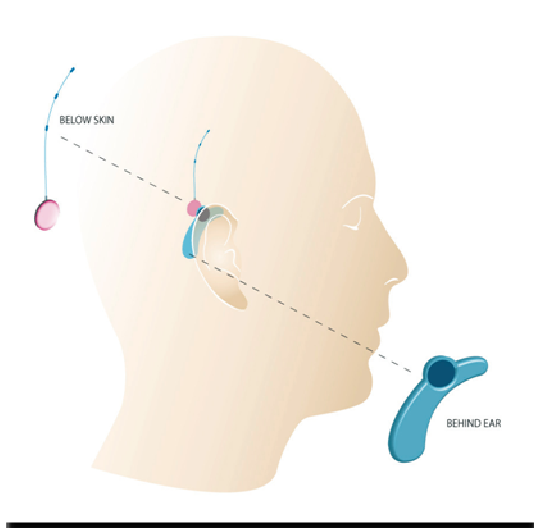


Figure 1: The Hypo-Safe device suitable for long term recording and real-time signal processing

The lead-time from significant EEG changes to severe cognitive dysfunction is in >90% of the cases long enough for the patient to correct hypoglycemia. The use of subcutaneous electrodes provides an alternative to surface electrodes and has enabled the development of a device that can be carried 24 h/day.

The device is still under development and the prototype is currently undergoing clinical trials. The commercial device is expected on the market in the second half of 2009.

Hypo-Safe possesses and have access to the foremost scientific competences within mathematical models for complex data analysis. The subcutaneous method of monitoring has demonstrated to provide a remarkably high quality of data which makes it possible to recognize typical EEG patterns that are unlikely to be detected with surface electrodes over longer periods.

By use of subcutaneously placed electrodes and real-time signal processing the Hypo-Safe device enables the recording of specific changes in EEG, processing by a general mathematical algorithm and the generation of a significant hypoglycemia signal which can be detected before the development of clinical hypoglycemia with cognitive failure.

### Five user benefits:

1. Provides a genuine protection against hypoglycemia:
  - Ensures the detection of all hypoglycemia events
  - Provides alarms in time to react
  - Does not stress the user with false positive alerts
2. Does not require calibration
3. Has no replacement parts
4. Does not compromise the comfort of the user
5. Is a simple and long lasting solution