Human test condition filing format

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Item	Condition / Information
1. Background and purpose of the experiment	**Background:** It was hypothesized that ELF-EMF measurements may be able to predict the onset of acute medical events such as hyo and/or hyperglycemia. In a previous experiment on a Type 1 DM patient, applying AI/ML algorithms to signals obtained two TDK Nivio xMR sensors we discovered unique signals and waveforms that corresponded to hypo and hyperglycemic events independently. These signals predicted events 15-30 minutes prior to the event. While these signals do not correspond to blood glucose measurements, we hypothesize that they are reflective of mitochondrial function. **Purpose**: We would like to confirm and expand on our previous findings that the AI/ML analysis of ELF-EMF signals can non-invasively predict hypo and hyperglycemic events.
2. Method of the experiment (Diagram explains the scene of the experiment, including the configuration of the equipment and the placement of subjects and operators)	The study recruits two populations: Nine (9) healthy individuals and ten (10) Type 1 diabetics who have a CGM. The experimental procedure involves a screening visit followed by an intervention day. On this day, for both groups, sets of Nivio/Migne sensors will be placed on the skull, forearm and over the RUQ (liver area), and another set of sensors placed in the room for background measurements. The normal subjects will then have ELF-EMF measurements collected for 2-3 hours. The DM patients will have two IV lines inserted, one for insulin and the other for glucose. The insulin and glucose lines will be used to stabilize normoglycemic levels. Subsequently, an insulin drip will be used to achieve hypoglycemia, and then a glucose laden drink will be given to induce hyperglycemia. Insulin drip will then be used to stabilize normoglycemia and the subject will be discharged. The entire procedure is estimate at 4-6 hours. ELF-EMF signals will be collected on a PC and transferred via the cloud to Evolution Inc for AI/ML signal processing. Please see diagram on slide 3 and attachment “Device Setup 0724”.
3. Expected risks and countermeasures (consideration for human rights, equipment safety, personal information protection, EMC, etc.)	This trial protocol received Helsinki ethics committee approval (File # 0529-23-HMO) on March 6, 2024 but we were requested to receive additional approval from Israeli Ministry of Health (MOH). Israeli MOH requested that we complete an Investigator brochure (attached “IB-TDN-00 v1 Investigator Brochure”) in which specific issues on expected risks and countermeasures are described in Chapters 3-6. This document was filed with Israeli MOH in June 2024. As a result of our filing and subsequent site visit in July 2024, Israeli MOH requested that we perform a safety study to satisfy IEC 60601-1:2005/AMD1:2012/AMD2:2020 and IEC 60601-1-2:2014/AMD1:2020 standards. This test was performed on August 15, 2024 and the final clearance letter received on August 27, 2024 (attachment #2 “L300150.01 Tedence Check-Up letter”). The final revised documents completing all Israeli MOH requirements were submitted to the Hadassah University Helsinki Committee on September 6, 2024. We are currently awaiting final approval by the CEO of Hadassah University Medical Center. Once final approval is received, we are ready to begin the pilot clinical trial. This trial will be conducted at the Diabetes Unit of Hadassah Medical Center, ensuring adherence to regulatory standards and ethical guidelines. Subjects will be required to sign a trial consent form which describes the protocol and device design. Clinical trial insurance is required to perform the trials. Safety assessments focus on monitoring device-related and general adverse events, including the effects of the ELF-EMF sensing device and complications from the procedure itself. Subjects will be tested in a hospital setting and will be constantly monitored throughout the duration of the study by physicians of the Diabetes Unit
4. About the Subjects of the Experiment	a) Only the applicant himself / herself b) Including non-applicants
5. About specimens and data handled	b) Individuals cannot be identified

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Item	Condition / Information
6. Experiment place	Hadassah University Hospital Kalman Ya'akov Man St Diabetes Unit Jerusalem, Israel
7. Stakeholders (If you will promote the human test with other stakeholders, please share us the information)	Yes • Evolution Inc • Ronen Tal Botzer, b) Only sharing experimental results
8. Experimental period	2024/10-2025/03
9. Paper Publication Plan	Yes Morris Laster, MD, Pavel Ginzburg, PhD (Tedence) Ronen Tal Botzer (Evolution Inc) Prof Gil Lebovitz, Olga Foiering, MD, Genya Hananel, MD (Hadassah University Medical Center)

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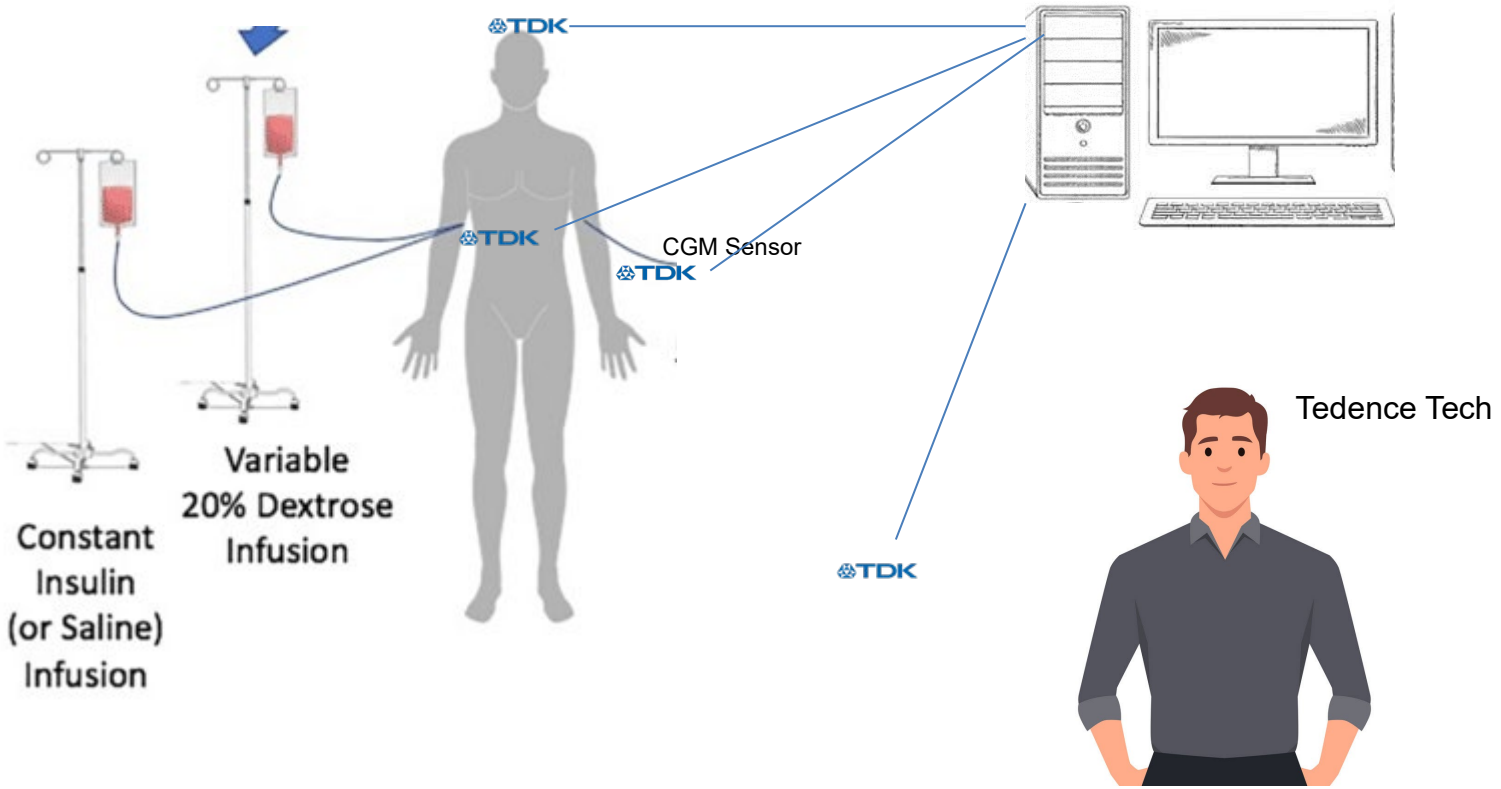
Method of the experiment*

Diagram explains the scene of the experiment, including the configuration of the equipment and the placement of subjects and operators

Medical Staff



TDK Represents TDK Nivio/Migne Sensor Placement

1. Head
2. RUQ Abdomen
3. Forearm
4. Placed in room

See Attachment #3 “Device Setup 0724”