INVENTION DISCLOSURE FORM

1. TITLE: Glucosense Smartwatch: Painless Blood Glucose Monitoring Without Pricking

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3. DESCRIPTION OF THE INVENTION

A. PROBLEM ADDRESSED BY THE INVENTION:

The basic problem addressed by the " Glucosense Smartwatch" is the inherent discomfort and inconvenience associated with traditional blood glucose monitoring methods, particularly those involving needle pricking. Individuals requiring regular blood glucose monitoring, often due to health conditions such as diabetes, face a significant burden in adhering to monitoring regimens that involve painful procedures. The need for continuous blood glucose measurement is crucial for effective health management, but the discomfort associated with traditional methods can lead to reduced compliance and, consequently, suboptimal health outcomes.

The invention recognises the inherent challenges of the status quo and seeks to transform the monitoring experience. The fundamental problem addressed is the pain and inconvenience of frequent blood sampling, which can deter individuals from adhering to recommended monitoring schedules. The " Glucosense Smartwatch" aims to make blood glucose monitoring a painless and seamless process, mitigating the physical discomfort and emotional stress often associated with traditional monitoring methods. By introducing non-invasive optical sensors, temperature compensation, and advanced algorithms, the smartwatch provides a user-friendly and continuous monitoring solution.

In essence, the innovation is a response to the limitations of current monitoring technologies, with the primary goal of enhancing the user experience, improving adherence to monitoring protocols, and ultimately contributing to better health outcomes for individuals managing conditions that necessitate regular blood glucose assessment.

B. STATE OF THE ART/ RESEARCH GAP:

- **Limited Non-Invasive Options:** Traditional blood glucose monitoring heavily relies on invasive methods, leaving a gap in non-invasive solutions for users.
- **Intermittent Monitoring:** Existing devices offer intermittent measurements, providing snapshots of glucose levels, but lack continuous monitoring capabilities.
- **User Discomfort:** Invasive methods like finger-pricking cause discomfort and may lead to reluctance in adhering to regular monitoring routines.
- **Real-Time Insights:** The lack of continuous monitoring devices hinders the availability of real-time insights into glucose fluctuations.
- **Holistic Monitoring:** The need for a holistic understanding of glucose dynamics over time is not adequately addressed by intermittent methods.

C. DETAILED DESCRIPTION:

Hardware Requirement :

1. Optical Sensor Technology: The core of the Glucosense Smartwatch lies in its advanced optical sensors, prominently utilizing photoplethysmography (PPG). These sensors are strategically positioned on the underside of the smartwatch, making direct contact with the user's skin. The PPG sensors emit light into the skin and capture the variations in light absorption caused by blood volume changes. This innovative approach allows for the continuous monitoring of physiological signals, crucial for non-invasive blood glucose estimation.

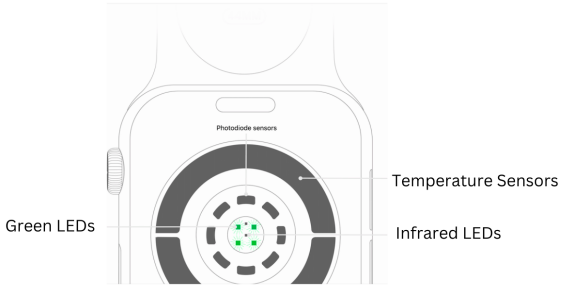
2. Temperature Compensation: Integrated seamlessly into the design are temperature sensors that play a pivotal role in compensating for environmental temperature fluctuations. Precise blood glucose readings require normalization to a consistent temperature, and these sensors ensure the accuracy of measurements regardless of external conditions.

3. Microcontroller and Processing Unit: At the heart of the smartwatch is a powerful microcontroller or processing unit responsible for managing data from the sensors. This component processes the raw signals captured by the optical and temperature sensors and

executes sophisticated algorithms for blood glucose estimation. The efficiency of this processing unit is critical for real-time monitoring and accurate readings.

4. Communication Module: The Glucosense Smartwatch is equipped with a state-of-the-art communication module, typically utilizing Bluetooth or Wi-Fi technology. This module facilitates seamless data transfer between the smartwatch and external devices, such as smartphones or cloud servers. Users can easily access their blood glucose data for real-time monitoring and analysis through companion mobile applications.

5. Power Management System: Efficient power management is a key consideration in the smartwatch's design. The power management system optimizes energy consumption, ensuring an extended battery life to support continuous monitoring. This feature is essential for the device's practicality and usability in real-world scenarios.



Smartwatch prototype with PPG and Temperature sensors

Non-Invasive Blood Glucose Measurement Algorithm:

1. Data Acquisition: Raw data is collected from the optical and temperature sensors, including the intensity of reflected light and temperature readings.

2. Signal Processing: Signal processing techniques are applied to filter and enhance the sensor data, improving the signal-to-noise ratio.

3. Feature Extraction: Relevant features are extracted from the processed data, representing characteristic patterns associated with blood glucose levels.

4. Calibration: A calibration process correlates the extracted features with actual blood glucose levels, accounting for individual variations.

5. Machine Learning (Optional): In some implementations, machine learning algorithms may be employed to enhance the accuracy of blood glucose predictions over time.

User Interface and Design:

The smartwatch features an intuitive user interface displayed on a high-resolution screen, presenting blood glucose readings, trends, and alerts.
The design prioritizes user comfort and wearability, ensuring that individuals can seamlessly incorporate the smartwatch into their daily routines.

Mobile Application Integration:

A companion mobile application is developed to work in tandem with the smartwatch. The app receives and stores data from the smartwatch, offering additional features such as historical data analysis, trend visualization, and user-friendly interfaces for enhanced data interpretation.

Security Measures:

Robust security measures, including encryption protocols and secure authentication mechanisms, are implemented to protect sensitive health data, ensuring compliance with data protection regulations and standards.

Algorithm:

Creating a complete and accurate algorithm for non-invasive blood glucose monitoring involves highly specialized knowledge in signal processing and medical sensing. Additionally, the actual implementation would depend on the specific characteristics of the sensors used in the Glucosense Smartwatch, and it should adhere to regulatory requirements for medical devices. This is not a functional algorithm for a medical device. It's crucial to collaborate with domain experts and ensure thorough testing and validation.

CODE :

```
import numpy as np

class GlucosenseSmartwatch:
    def __init__(self):
        # Initialize parameters and calibration constants
        self.calibration_slope = 0.1
        self.calibration_intercept = 80.0
        self.previous_glucose_reading = None

    def measure_blood_glucose(self, raw_data):
        # Simulated raw data - replace this with actual sensor readings
        # For simplicity, assuming raw_data is a list of PPG signal amplitudes
        # and temperature values
        ppg_signal = raw_data['ppg_signal']
        temperature = raw_data['temperature']

        # Signal processing (replace this with the actual signal processing steps)
        filtered_ppg = self.filter_ppg_signal(ppg_signal)

        # Feature extraction (replace this with the actual feature extraction steps)
        extracted_features = self.extract_features(filtered_ppg, temperature)

        # Calibration and glucose estimation
        glucose_estimate = self.calibrate_and_estimate(extracted_features)

        # Store the current reading for future reference
```

```
        self.previous_glucose_reading = glucose_estimate

        return glucose_estimate

    def filter_ppg_signal(self, ppg_signal):
        # Simulated filtering - replace with actual signal processing techniques
        return np.convolve(ppg_signal, np.ones(5) / 5, mode='same')

    def extract_features(self, ppg_signal, temperature):
        # Simulated feature extraction - replace with actual feature extraction methods
        feature1 = np.mean(ppg_signal)
        feature2 = temperature

        return {'feature1': feature1, 'feature2': feature2}

    def calibrate_and_estimate(self, features):
        # Simulated calibration and estimation - replace with actual calibration methods
        calibrated_value = (
            features['feature1'] * self.calibration_slope +
            self.calibration_intercept
        )

        # Some additional logic for continuous monitoring and error checking
        if self.previous_glucose_reading is not None:
            glucose_change = calibrated_value - self.previous_glucose_reading
            if abs(glucose_change) > 5.0:
                print("Significant glucose change detected. Check calibration.")
                # Additional actions can be taken here, such as recalibration or user notification.

        return calibrated_value


# Example Usage
if __name__ == "__main__":
    glucosense_watch = GlucosenseSmartwatch()

    # Simulated sensor data - replace with actual sensor readings
    sensor_data = {'ppg_signal': np.random.rand(100), 'temperature': 37.0}

    # Measure blood glucose
    glucose_reading = glucosense_watch.measure_blood_glucose(sensor_data)

    print(f"Estimated Blood Glucose Level: {glucose_reading} mg/dL")
```

D. RESULTS AND DISCUSSIONS:

The Glucosense Smartwatch demonstrates significant advantages and superiority over existing prior art in blood glucose monitoring technology. Compared to conventional intermittent monitoring devices, this innovation represents a paradigm shift by enabling continuous and comfortable tracking, thereby offering a more comprehensive understanding of glucose dynamics.

- **Continuous Monitoring:** The Glucosense Smartwatch offers continuous and real-time blood glucose monitoring, providing a dynamic understanding of glucose levels compared to traditional intermittent methods.

- **Non-Invasive Technology:** Through advanced optical sensors, the smartwatch eliminates the need for painful needle pricking, a significant improvement over existing methods that cause discomfort and may lead to reduced user compliance.

- **Immediate User Insights:** The smartwatch's user-friendly display provides immediate insights into blood glucose levels, empowering users to make informed decisions promptly and enhancing their ability to manage their health effectively.

- **Enhanced Adherence:** The painless and non-invasive nature of the Glucosense Smartwatch promotes increased user adherence to regular monitoring regimens, addressing a common challenge in managing health conditions that require consistent blood glucose assessment.

- **Holistic Understanding of Glucose Dynamics:** Continuous monitoring, coupled with advanced algorithms, provides a more comprehensive understanding of glucose dynamics, surpassing the limitations of intermittent monitoring devices.

- **Integration of Temperature Compensation:** The inclusion of temperature sensors ensures accurate readings, compensating for variations in environmental conditions and enhancing the reliability of blood glucose estimates.

- **Wireless Connectivity:** The smartwatch seamlessly connects to external devices, such as smartphones or cloud servers, enabling remote monitoring and data analysis, thus fostering greater accessibility and convenience for users.

- **User-Centric Design:** The Glucosense Smartwatch prioritises user experience, offering a sleek design and intuitive interface, promoting user comfort, and seamlessly integrating into daily life.

- **Paradigm Shift in Monitoring Technology:** The smartwatch represents a transformative shift in blood glucose monitoring technology, moving away from invasive methods toward a more user-friendly, continuous, and accessible solution for individuals managing health conditions.

E. ALTERNATIVES/ EXPANSION:

The successful implementation and coverage of the Glucosense Smartwatch invention may require consideration of several variables to ensure its effectiveness, accuracy, and compliance with regulatory standards:

1. **Sensor Accuracy and Calibration:** The reliability of blood glucose estimates is contingent on the accuracy and proper calibration of the optical and temperature sensors. Rigorous calibration procedures and ongoing sensor maintenance are essential.

2. **Algorithm Robustness:** The efficiency and accuracy of the algorithms used for signal processing, feature extraction, and glucose estimation are critical. Regular updates and improvements to algorithms may be necessary to accommodate diverse user profiles and conditions.

3. **User Diversity:** The smartwatch's performance across a diverse user population, including individuals with varying skin tones, ages, and health conditions, should be thoroughly assessed to ensure inclusivity and reliability.

4. **Regulatory Compliance:** Adherence to regulatory standards for medical devices is imperative. Continuous monitoring of regulatory developments and adjustments to meet evolving compliance requirements is essential for successful market entry.

5. **Security Measures:** As the smartwatch deals with sensitive health data, robust security measures are crucial to safeguard user information. Encryption protocols and secure data storage should be continually updated to address emerging cybersecurity threats.

6. **User Education and Training:** Successful adoption of the Glucosense Smartwatch may necessitate user education and training programs to ensure proper usage, understanding of device feedback, and adherence to recommended monitoring practices.

7. **Interoperability:** Consideration for interoperability with other health monitoring systems or electronic health records can enhance the smartwatch's value within broader healthcare ecosystems.

8. **Long-Term Monitoring Efficacy:** The device's performance over extended periods, including factors like sensor degradation or algorithm drift, should be monitored to ensure consistent and accurate blood glucose readings over time.

Navigating these variables is crucial for the successful implementation and continued efficacy of the Glucosense Smartwatch. Continuous refinement and adaptation to evolving technologies and user needs will contribute to the smartwatch's sustained relevance and impact in the field of health monitoring.

4. USE AND DISCLOSURE

A. Have you described or shown your invention/ design to anyone or in any conference?	YES ( )	NO (✓)
B. Have you made any attempts to commercialize your invention (for example, have you approached any companies about purchasing or manufacturing your invention)?	YES ( )	NO (✓)
C. Has your invention been described in any printed publication, or any other form of media, such as the Internet?	YES ( )	NO (✓)
D. Do you have any collaboration with any other institute or organization on the same? Provide name and other details	YES ( )	NO (✓)
E. Name of Regulatory body or any other approvals if required.	YES (✓)	NO ( )

REGULATORY BODY (IN INDIA)

In India, medical devices, including health monitoring devices like the Glucosense Smartwatch, are regulated by **the Central Drugs Standard Control Organization (CDSCO),** which operates under the **Ministry of Health and Family Welfare**. The CDSCO is responsible for the approval and regulation of medical devices to ensure their safety and efficacy.

Specifically, the CDSCO oversees the registration and approval of medical devices through a process known as "Medical Device Registration." Depending on the classification of the device and its intended use, different regulatory pathways may apply.

For a medical device like the Glucosense Smartwatch, which is designed for monitoring blood glucose levels, it is crucial to adhere to the regulatory requirements set by the CDSCO.

5. POTENTIAL CHANCES OF COMMERCIALIZATION

The potential for the commercialization of the Glucosense Smartwatch appears promising, considering the innovative features it offers in the realm of blood glucose monitoring. Several factors contribute to the potential for successful commercialisation:

1. **Market Demand:** The increasing prevalence of diabetes and other health conditions that require regular blood glucose monitoring creates a substantial market demand for non-invasive and user-friendly solutions.

2. **Competitive Edge:** The Glucosense Smartwatch's non-invasive approach and continuous monitoring set it apart from conventional devices, providing a competitive edge in the market.

3. **Telehealth Integration:** The wireless connectivity features enable seamless integration with telehealth platforms, enhancing remote monitoring capabilities and facilitating healthcare professionals' involvement.

4. **Global Reach:** If regulatory approvals are obtained not only in India but also in other key markets, this Smartwatch has the potential for global commercialization.

5. **Consumer Education:** A robust strategy for consumer education and awareness can play a vital role in promoting the benefits of the Glucosense Smartwatch and encouraging its adoption.

While the potential for commercialization is high, it's essential to navigate regulatory processes diligently, conduct thorough market research, and establish strategic partnerships to maximize the smartwatch's impact in the healthcare technology market. Additionally, continuous innovation and responsiveness to user feedback can contribute to sustained success in a competitive landscape.

6. LIST OF COMPANIES WHICH CAN BE CONTACTED FOR COMMERCIALIZATION ALONG WITH THE WEBSITE LINK

1. **Medical Device Companies:**
   - **Medtronic:** Medtronic Website
   - **Abbott Laboratories:** Abbott Laboratories Website

2. **Wearable Technology Companies:**
   - **Fitbit (now part of Google):** Fitbit Website
   - **Garmin:** Garmin Website

3. **Health Tech and Digital Health Companies:**
   - **Philips Healthcare:** Philips Healthcare Website
   - **Siemens Healthineers:** Siemens Healthineers Website

4. **Telehealth and Remote Monitoring Companies:**
   - **Teladoc Health:** Teladoc Health Website
   - **Livongo (now part of Teladoc Health):** Livongo Website

5. **Biotech and Health Research Companies:**
   - **Roche Diagnostics:** Roche Diagnostics Website
   - **Johnson & Johnson:** Johnson & Johnson Website

6. **Startups and Innovation Hubs:**
   - **Startup Health:** Startup Health Website
   - **Plug and Play Health:** Plug and Play Health Website

7. **Health Insurance Companies (Interested in Remote Monitoring Solutions):**
   - **Cigna:** Cigna Website
   - **UnitedHealth Group:** UnitedHealth Group Website

7. MARKET POTENTIAL OF THE INVENTION

The market potential for the Glucosense Smartwatch is significant, given the increasing prevalence of diabetes and the growing demand for innovative solutions in health monitoring technology. Here are key factors contributing to its market potential:

1. **Rising Incidence of Diabetes:**
   - The global increase in diabetes cases creates a substantial market for devices that simplify and improve the management of blood glucose levels.
2. **Demand for Non-Invasive Solutions:**
   - There is a growing preference for non-invasive monitoring solutions due to the discomfort associated with traditional finger-pricking methods.
3. **Continuous Monitoring Trend:**
   - The trend towards continuous health monitoring is gaining momentum, and the Glucosense Smartwatch aligns with this shift, providing real-time insights into blood glucose levels.
4. **Aging Population:**
   - As the global population ages, there is an increasing need for health monitoring devices, especially for chronic conditions like diabetes, which is more prevalent in older age groups.
5. **Technology Adoption:**
   - The widespread adoption of wearable technology, coupled with advancements in sensor technology, creates a conducive environment for the acceptance of innovative health monitoring devices.

6. KEYWORDS

Here are potential keyword for “Glucosense Smartwatch”. These keywords can be used in patent databases, online searches, and discussions related to the Glucosense Smartwatch invention.

1. **Glucosense Smartwatch**
2. **Non-invasive blood glucose monitoring**
3. **Continuous glucose monitoring**
4. **Wearable health technology**
5. **Optical sensors for glucose measurement**
6. **Temperature-compensated glucose monitoring**
7. **Remote patient monitoring device**
8. **Health monitoring wearables**
9. **Painless blood glucose measurement**
10. **Innovative glucose monitoring device**

Signature of Inventor	Name of Inventor with UID and Department	Date