BodiGuide Continuous Fluid Monitor

Technical Overview

BodiGuide

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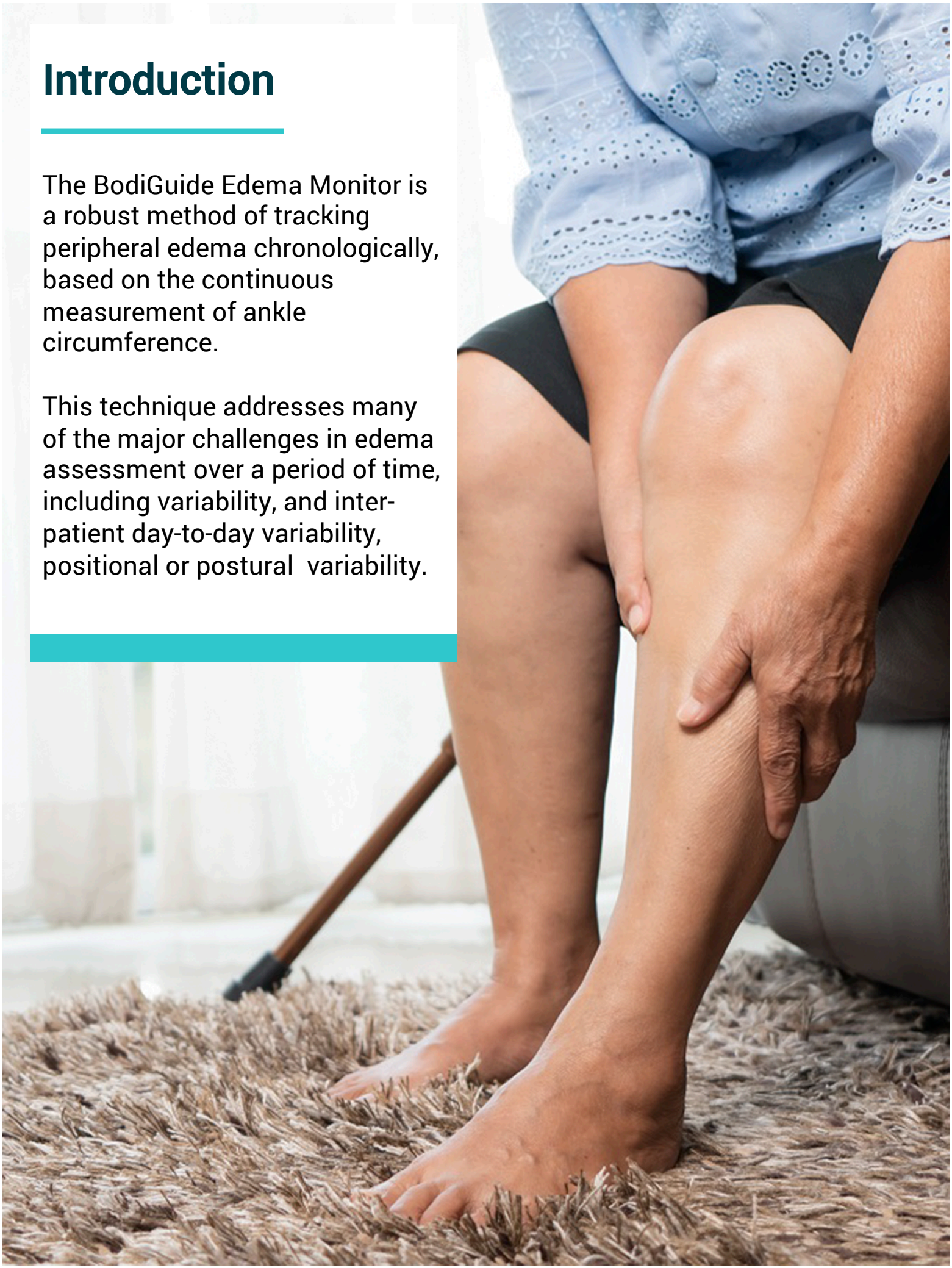
Introduction

The BodiGuide Edema Monitor is a robust method of tracking peripheral edema chronologically, based on the continuous measurement of ankle circumference.

This technique addresses many of the major challenges in edema assessment over a period of time, including variability, and inter-patient day-to-day variability, positional or postural variability.



A Direct Measure of Fluid Volume

Peripheral edema (PE) is an accumulation of fluid in the interstitial space that occurs as the capillary filtration exceeds the limits of lymphatic drainage, producing noticeable changes in ankle size .

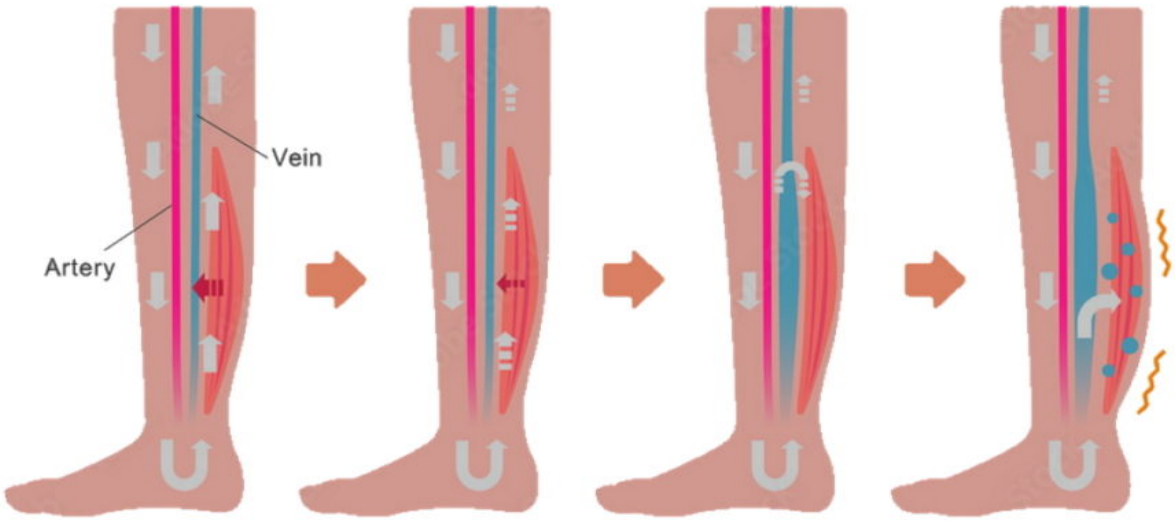
Fluid compartments in the human body are divided between the intracellular and extracellular spaces. The extracellular space constitutes about one-third of total body water, which is further divided into intravascular plasma volume (25%) and the extravascular interstitial space (75%).

The fluid balance between these compartments is maintained by hydrostatic pressures and oncotic pressures. The physiological mechanism causing peripheral edema occurs when this balance is altered by any one or more of the following factors:

- Increased intravascular hydrostatic pressure
- Decreased intravascular or plasma oncotic (colloid osmotic) pressure
- Increased vascular permeability

The lymphatic system collects fluid and filtered proteins from the interstitial space and returns that back to the vasculature.

Any disturbance in this delicate homeostasis resulting in net filtration out of the vascular space or impaired return of fluid by lymphatics leads to the accumulation of fluid in the interstitial space.



Measurement Technology

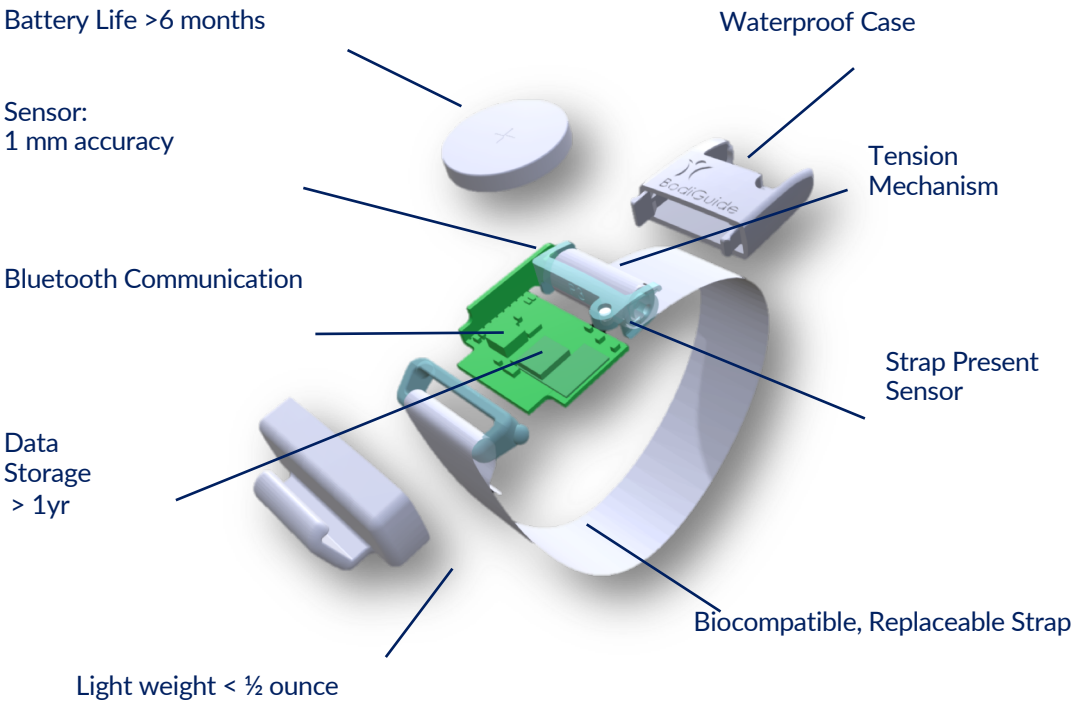
- **Accuracy** – A combination of position, orientation and circumference sensors, plus proprietary calibration techniques, enable +/- 0.5 mm (+/- 0.2 in) measurement accuracy

- **Measurement Location** – The device automatically locates the optimal position for measuring interstitial fluid volume on the patient's ankle, ensuring both accuracy and long-term repeatability.

- **Baseline Modeling** – Measurement accuracy is sufficient to distinguish fluid loading events and trends from normal circumference variation.

- **Tension without compression** – The device maintains optimal tension during the entire range of expansion and contraction independent of ankle size such that compression of the limb does not occur.

- **Limb Orientation** – The anklet includes an accelerometer for capturing limb orientation and patient activity.



Patient Comfort

Employing a comprehensive set of patient-friendly features and attributes:

- Lightweight
- Unobtrusive
- Battery life greater than 6 mo.
- Water proof
- Automatic data capture
- Custom analysis

The BodiGuide Edema Monitor enables patients, healthcare professionals and caregivers to effortlessly quantify changes in fluid retention.

Passive

Waterproof

Comfortable

Reliable

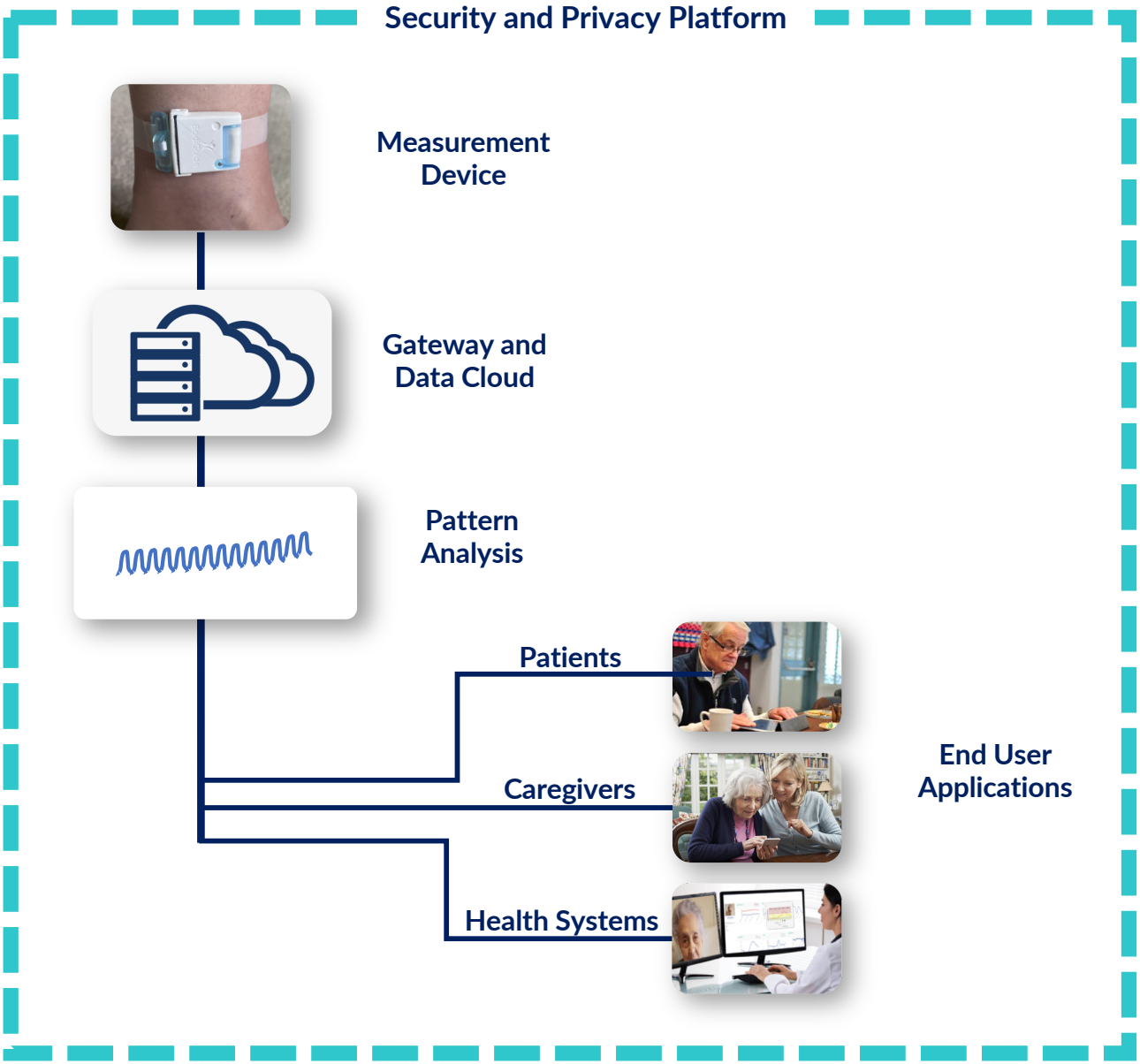
System Architecture

The anklet communicates to a medical grade cellular gateway via Bluetooth. The gateway can also collect data from other commercial devices such as a weight scale or blood pressure cuff.

The cellular gateway relays data to the BodiGuide Cloud for analysis.

Pattern recognition identifies deviations from the patient's normal baseline due to fluid retention or loss.

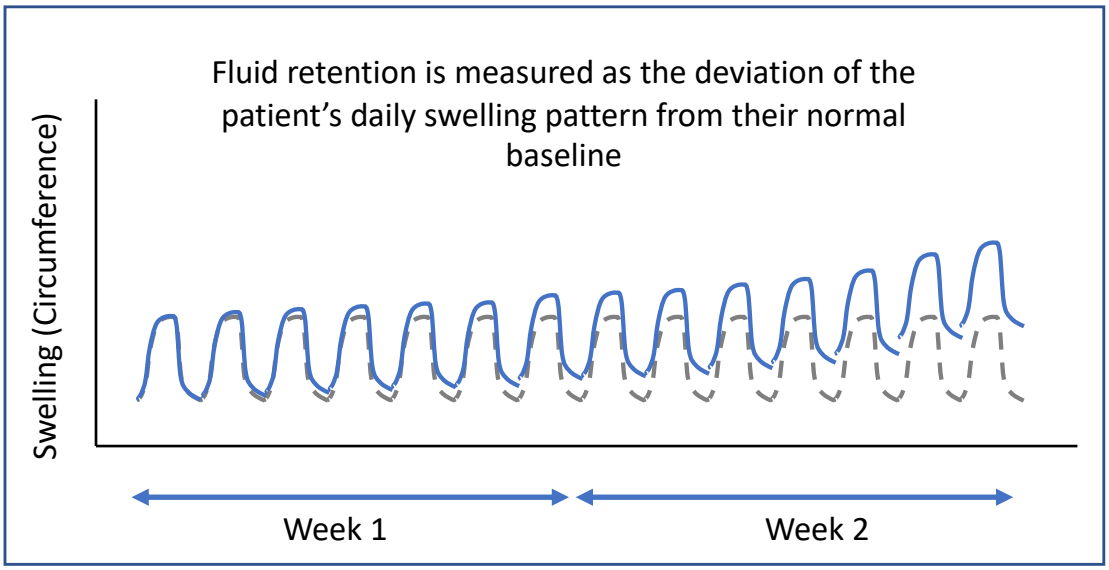
Results are then communicated to the patient, caregivers, and clinicians.



Pattern Recognition

The BodiGuide system provides continuous measurement and monitoring of ankle swelling and recognizes patterns that deviate from the patient's normal patterns or baseline.

When these patterns are associated with prescribed medication, the fluid volume history can provide the clinician with the opportunity to determine therapeutic effectiveness and optimize treatment over the natural course of the disease.



Increased Visibility

With the ability to continuously monitor fluid retention, chronic conditions can be detected several weeks before patients experience acute symptoms that might require hospitalization.

This provides clinicians with a therapeutic window of time for effective intervention.

Data Security and Privacy

The BodiGuide platform includes a robust security framework to safeguard sensitive healthcare data throughout its lifecycle.

This novel security architecture is tailored specifically for IoT-based healthcare data management systems. It protects the entire data processing pipeline, encompassing data collection at the edge, data in-motion through cloud-based services for analytics and storage and data visualization on a UI portal hosted on a cloud server.

This architecture addresses key security challenges at each stage of the data management process.