Remote Personalized Continuous Outpatient Monitoring of High-Risk Individuals Affected by COVID-19

Hospital beds during the COVID-19 pandemic are in short supply. Clinical-grade wearable biosensors and advanced physiology analytics offer the opportunity to monitor patients at home, including:

- COVID-19 positive/suspected who are high-risk (>50 yo w/ at least one co-morbidity) but not acute enough to be hospitalized
- Hospitalized COVID-19 patients who are stable enough to be discharged but who have not yet had two negative tests >24 hours apart
- High-risk heart failure/COPD/immunocompromised patients who may not be COVID-19 but at risk of exacerbation

**pinpointIQ® solution for personalized continuous remote monitoring of high-risk patients:**

- **PATIENT/PARTICIPANT**
  - Patients are provided clinical-grade disposable biosensors and a smartphone for data transmission and symptom tracking

- **CLOUD-BASED PLATFORM**
  - Data continuously streams to the cloud where FDA-cleared personalized analytics detect physiological anomalies

- **INSIGHTS**
  - Individual patient insights and alerts
  - Alerts are generated and presented to a clinician to enable proactive outreach to patient and timely intervention

**Continuous Biosensor Monitoring + Advanced Personalized Analytics**

Remote monitoring system can be provided in person (available at larger population centers) or overnight delivered directly to patient home.

- **Sensor patch - VitalPatch® (Vital Connect, Inc)** is an FDA 510(k)-cleared chest-worn disposable sensor patch with a 5-day battery life, waterproof.
- Continuous heart rate, heart rate variability, temperature, arrhythmia burden, respiratory rate, gross activity, walking, sleep, body tilt, and body posture.
- Android phone equipped with a conventional cellular data plan. Data from the sensors are continuously streamed to the phone via Bluetooth.
- In addition to transmitting physiological data, the app also may present questionnaires to the patient that are answered directly within the app.
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FDA-cleared Artificial Intelligence-based analytics do the heavy lift of data analysis

• **Secure cloud.** The physIQ platform is securely hosted in the Google cloud. PhysIQ Cloud-based IT platform (physIQ mobile app, IT platform, Clinician User Interface) are FDA Class I medical device.

• **FDA-cleared vitals.** The vital signs algorithms ingest continuous biosensor telemetry (ECG, Accelerometry, etc.) and generate a variety of vital signs using FDA-cleared algorithms. These analytics are FDA 510(K) cleared Class II-regulated medical device.

• **Personalized automated anomaly detection.** physIQ’s Multivariate Change Index, or “MCI,” is a machine learning algorithm that models each patient’s personalized baseline using their own vital sign patterns. This personalized model then serves as a dynamic baseline for detecting physiological vital sign behavior may be predictive of clinical deterioration.

• **Automated system-generated alerts** indicate when a patient’s physiology may be deteriorating, based on personalized analytics.

• **Scalable clinical workflow.** Clinical navigator (or pre-determined clinical team member) calls patient if any alerts are triggered.

Clinical evidence supporting the pinpointIQ® continuous remote monitoring solution

Continuous Wearable Monitoring Analytics Predict Heart Failure Exacerbation: The LINK-HF Multicenter Study Circ Heart Fail. 2020;13:e006513. DOI: 10.1161

• **CONCLUSION:** Continuous biosensor data and personalized machine learning-based analytics predicted heart failure exacerbation up to 10 days in advance and, for exacerbations related to other conditions (e.g. pneumonia, COPD, sepsis) up to 12 days in advance.


• **CONCLUSION:** In this proof of concept study, we were able to demonstrate that a portable, deployable system for continuous vital sign monitoring via a wireless, wearable sensor supported by a sophisticated, personalised analytics platform can provide high-acuity monitoring with a continuous, objective measure of physiological status of all patients that is achievable in virtually any healthcare setting, anywhere in the world.

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