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### **Healthcare Market Updates**

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Weekly Newsletter Issue 19 18<sup>th</sup> September 2018

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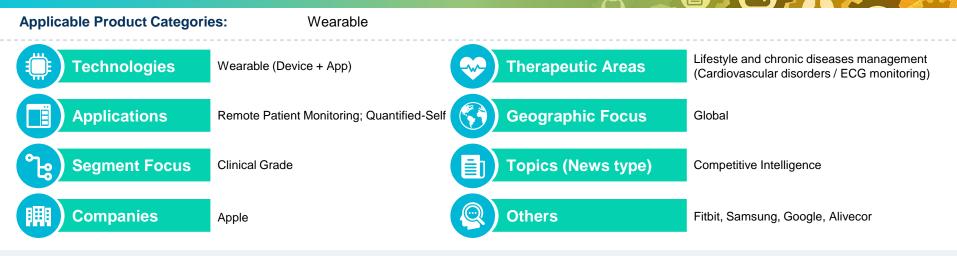
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## Apple Watch Series 4 is first consumer device to receive FDA clearance for ECG monitoring – September 12, 2018 (1/6)



#### ANALYST TAKE:

- Synopsis: The Apple Watch Series 4 has received clearance from the U.S. Food and Drug Administration to operate as an over-the-counter ECGmonitoring device, becoming the first device available to consumers over the counter to offer the functionality.
- Industry Need: As per WHO estimates, 7.3 million people die of cardiovascular diseases (CVD), particularly heart attacks and strokes every year globally. For example, heart disease has been the biggest killer in America since 1920 and involves spending of more than \$110 billion/year. However, among all the deaths caused by CVD, about two-thirds of them happen in out-of-hospital settings. This demands robust remote monitoring solutions such as wearables to promote preventive care practices. For example, as per a Mayo Clinic study (2015), digital health intervention among early-stage CVD population can lead to a 40% relative risk and 7.5% absolute risk reduction in CVD events, hospitalizations and deaths. This in turn is driving the demand for digital remote patient monitoring ECG solutions comparable to industry gold standards to promote preventive care practices.

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## Apple Watch Series 4 is first consumer device to receive FDA clearance for ECG monitoring – September 12, 2018 (2/6)

- Value Proposition: Approval from the FDA for the Apple Watch's electrocardiogram functionality makes it one of the only devices on the market to provide
  its users EKG readings. Typically ECG devices are not available for purchase by consumers, making the Apple Watch Series 4 an exception. The new
  Apple Watch now has electrodes in the sapphire crystal and digital crown, allowing users to take an ECG at any time using the included app. All ECG
  recordings are stored in the Health app, and can be shared with healthcare professionals at a later time. The ECG functionality will be available at first to
  customers in the United States, with Apple also working to bring the feature to other markets at a later time.
- Frost & Sullivan views 2018 as a milestone year for Apple's deeper penetration in the healthcare space. Early this year, Apple made a serious healthcare debut with the release of their health records API across a growing list of healthcare institutions (90+) to support health records on the iPhone. The recent FDA approval for Apple's Watch Series 4 is a cherry topping on its continuous commitment to make its mark in the vetted clinical-grade wearables arena. In fact, Apple is the first consumer-tech company in FDA's 2017 'fast track' program to come out as a winner among its competition (e.g. Google, Samsung and Fitbit). Given all these developments for Apple during 2018, Frost & Sullivan believes, Apple has carved a niche differentiating itself from competing consumer tech companies to finally reposition it as a true medical-grade device and solutions providers.
- Having said that, Frost & Sullivan also anticipates a tough competition for Apple watch's ECG monitoring value proposition given there are at least half a dozen other FDA approved (medical-grade) wearables/chest patches devices already competing in this space (e.g. Alivecore, BioTelemetry, CardioSecur, MC10, iRhythm, Bardy Diagnostics). Moving forward it will be interesting to see how Apple continue its ambition to further extend deeper by adding new vital-signs and technologies to further its wearable strategy (e.g. CGM, BP, Apple glasses, AirPods). More importantly, the future differential value proposition for Apple will heavily pivot on its strategy to move beyond the device play and integrate its Watch Series 4 with existing iPhone applications (e.g. health records API, ResearchKit and CareKit) to monetize the data services.
- Additionally, it will be interesting to watch how Apple makes moves to avoid potentially conflicting market positioning for the Watch Series 4, given its existing collaboration with companies such as <u>Alivecor</u> (KardiaBand paired with Apple watch) to monitor clinical-grade EKG.
- Target End-User: Healthcare Consumers, Insurance and Employee Health Programs, Clinical Trials

### Apple Watch Series 4 is first consumer device to receive FDA clearance for ECG monitoring – September 12, 2018 (3/6)

#### **Additional Insights:**

#### Specs

Price: \$399 Device Type: Smart watch Display Type: LTPO AMOLED Heart Rate: PPG heart rate sensor (with a tweak to provide notification on not just high heart rate, but also low heart rate). PPG operation: 24/7 Accelerometer: Yes Gyroscope: Yes GPS: Yes Steps Tracking, auto exercise detection: Yes Basic sleep tracking: Yes Sleep staging and insights: No VO2 Max: No HRV based stress score: No Battery Life: 1 day

#### **Business models**

[Please also read the partnerships point below] OTC sales mean that Apple will continue to sell through direct to consumer channels. No information has been publicly released about Apple pursuing other consumers (hospitals, senior living facilities, etc.), and we feel that the Apple Watch may not have all features that can cater to these customers' needs - fall detection and 1-lead ECG are basic features (definitely not sufficient for hospitals which have several clinical-grade devices already available).

## Apple Watch Series 4 is first consumer device to receive FDA clearance for ECG monitoring – September 12, 2018 (4/6)

Also, Apple CTO Jeff William's claim that "this is the first ECG product offered over the counter, directly to consumers" is not totally accurate given companies such as AliveCor and Cardiac Designs both already got over-the-counter (OTC) clearance from the agency in 2014 and 2013 respectively. Why did the FDA then provide a De Novo clearances status rather than a regular Class 2 filing citing existing best-in-class devices? - As per the FDA spokesperson, "The ECG App is the <u>first software-only ECG device</u> that creates, analyzes, and displays ECG data for [OTC] use." Essentially, the key differentiation for Apple is that, the new app is intended to be used with the Series 4 Apple Watch as a single product unlike other ECG apps (e.g. AliveCor) that need 3rd party compatible smart phones or peripheral devices (e.g. finger pad or wrist sensor).

**Price Point Comparison**: In the US market, ECG check monitor is normally available for \$129. Companies such as AlievCor and Cardiac Designs offer their current ECG smartphone hardware at \$99 (approx.). Given this, Apple Watch 4 priced at \$399 may be a barrier for average consumers to purchase the hardware needed for Apple's ECG app.

#### **US FDA**

This is the first approval coming from the 2017 Fast Track program, and clubbed with other news (Alivecor's breakthrough device designation for noninvasive blood potassium or hyperkalemia screening, for example) points to increasing trust and inclination towards such devices. We would expect more such approvals in the coming 12-18 month timeframe.

It also important to note that, the FDA De Novo clearance refers specifically, and exclusively, to Apple's software algorithm (app) that can predict atrial fibrillation from heart rate data, and not specifically clearing the Apple Watch 4, as a medical device. This means from a regulatory view, Apple Watch 4 will still fall under consumer health device category. This is also in line with Tim Cook's earlier statement that they would not want to put the smartwatch through the time-consuming regulatory processes of the FDA.

#### Clinical Studies (Apple submitted as part of its FDA clearance application):

Study 1: Apple tested the watch in more than 580 people, half of whom had atrial fibrillation. The app couldn't read about 10% of the heart rhythm recordings in the study. When it looked at the rest, though, the app was very accurate: It caught more than 98% of people with atrial fibrillation, and correctly told people that they didn't have the condition 99.6% of the time.

## Apple Watch Series 4 is first consumer device to receive FDA clearance for ECG monitoring – September 12, 2018 (5/6)

Study 2: Stanford's Apple Heart Study that examined 226 people (22 years or older) for validating app data from Apple Watch to identify irregular heart rhythms, including those from potentially serious heart conditions such as atrial fibrillation. As part of this study, participants were asked to wear both the Apple Watch and a traditional, wearable (ePatch) heart monitor and move around normally for about a week. During the monitoring period, about 41% of people had an irregular heart rhythm or an event that looked like atrial fibrillation show up on their traditional monitors. In about 79% of those cases, the app also picked something up. Based on the initial study findings, the study team concluded that "positive predictive value" for Apple's EKG app to look for atrial fibrillation is about 45% (i.e. more than 50% of the time the app flags a problem, then, the app will be wrong). As per clinicaltrial.gov (ClinicalTrials.gov Identifier: NCT03335800), so far 500,000 subjects have been enrolled with current status of the study as 'Active, not recruiting' until January 31, 2019 as the end date. The above two studies (objective and results) further validated that, the FDA approval is limited to Apple software algorithm (app) only. Given that the clinical-grade ECG devices/apps for Atrial Fibrillation condition is already crowded, moving forward Frost & Sullivan anticipates Apple will be challenged by existing companies on future comparative effectiveness studies which is a common trend in this space to demonstrate clinical superiority influencing buying decisions (e.g. AliveCor vs. iRhythm; iRhythm Zio® XT patch vs. Bardy Diagnostics, CAM patch).

**Reimbursement:** In view of the above two clinical validation studies, Frost & Sullivan believes Apple Watch will continue as an OTC only product but not as a prescription medical device that generally qualifies for reimbursement (also because the app is cleared, not the smartwatch). However, this doesn't prevent Apple from being considered for CMS preventive services that are covered by Medicare (for Cardiovascular disease screenings and behavioral therapy) especially given the increasing adoption of Telehealth services in the US market.

#### **Target audience**

The ECG feature is limited to the US for now, and we think Apple will wait for a few months before targeting other regions.

Since it has fall detection features as well - the target audience is clear: 40 or 50+ for ECG, and elderly (60 or 65+) for fall detection + ECG, and of course all diagnosed cardiac patients for taking quick ECGs whenever required. [We would predict a soar in the sales of the Series 4 around Thanksgiving / Christmas, as gifts for the elderly.]

#### **Potential partnerships**

There are likely 2 options for Apple, in our opinion:

a) No partnerships - provide consumers with an additional 'value-add' feature of ECG, and let them take their results to their doctors, i.e. Apple plays no role downstream of taking an ECG. OR

b) Build an ecosystem to provide further services, like it did in its heart study with a partnership with American Well (one of the easiest routes possible where Apple does not take ownership / medical liability for medical support and guidance beyond the ECG).

#### Alivecor in that light

The 'partnership' with Apple was not exclusive and Alivecor only made accessories for Apple products. Alivecor has since responded with a 6-lead reader, capable of detecting 100 disease conditions, versus only AFib for Apple (<u>https://9to5mac.com/2018/09/17/alivecor-apple-watch-series-4-response/</u>), and Vic Gundotra @Alivecor believes their patents would make it difficult for any competitors to enter the market. a 1-lead ECG versus a 6-lead ECG, from a features perspective makes the Alivecor a winner - but more important is the question around any of these devices being brought in to clinical practice - a) will doctors trust this device enough, b) how do you enable the entire clinical care continuum to adopt this device [note, the earlier Alivecor products and the Apple watch (1-lead) are all OTC - a 6-lead product may or may not be OTC, depending on it's claim to diagnose 100 diseases <u>accurately</u> (i.e. it needs to be clinically validated).

At the moment, initial reactions aren't positive even for a 1-lead Apple Watch: the ECG feature created a stir, and doctors are wary of patients coming in more frequently for expensive tests to confirm the results - <u>https://bit.ly/2phUyeS</u> & <u>https://bit.ly/2xsOjJ7</u>.

Bottom line- Alivecor will continue innovating, so will Apple (and probably Fitbit too), but this entire nascent space needs to evolve for clinical validation and adoption.

# Could We Soon Be Using A Wearable Device For Regrowing Hair – September 14, 2018 (1/2)



#### ANALYST TAKE:

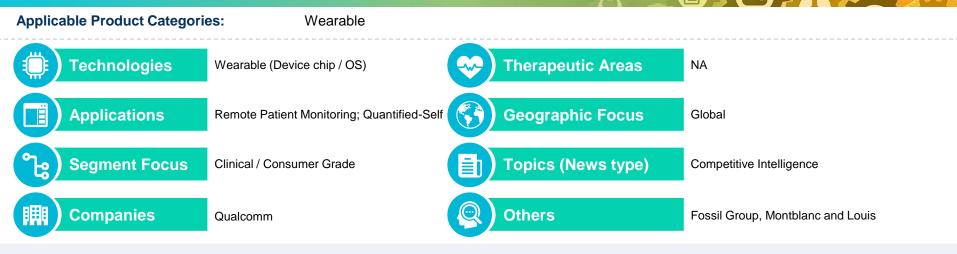
- Synopsis: A group of scientists have developed a flexible, wearable photostimulator that has proved successful in speeding up hair growth in mice at an experimental level.
- Industry Need: Hair loss, also known as alopecia or baldness is considered an aesthetic, psychological, and social issue among modern people. Based on
  industry estimates, the hair loss treatment market worldwide is pegged over \$2.8 billion in 2017. Similarly, the volume of surgical hair restoration
  procedures increased from 252,002 procedures in 2008 to around 397,048 in 2014. Given the increasing urbanization of human society leading to busy
  lifestyles, there has been an increasing demand for easy to use hair treatment devices, which cater to the changing needs of the customers. Frost and
  Sullivan believes devices that leverage emerging technologies and innovation will be key players in this market.

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# Could We Soon Be Using A Wearable Device For Regrowing Hair – September 14, 2018 (2/2)

- Value Proposition: Although laser-induced skin stimulation is utilized for hair-loss treatment, such treatment has significant drawbacks of high energy consumption, huge equipment size, and limited usage in daily life. As per ScienceDaily, researcher Keon Jae Lee and his colleagues have fabricated an ultrathin array of flexible vertical micro-light-emitting diodes (µLEDs) to demonstrate how a wearable photostimulator can be applied for hair-growth applications. The array consists of 900 red µLEDs on a chip slightly smaller than a postage stamp (20 µm thick). The device uses almost 1,000 times less power per unit area than a conventional phototherapeutic laser, and it does not heat up enough to cause thermal damage to human skin.
- The in-research prototype has been successfully tested at lab scale, and the results found that mice who wore the µLED patch for 15 minutes daily over a period of 20 days, showed significantly faster hair growth and longer length (results have been published in <u>ACS Nano</u>).
- Given current treatments option for hair loss include medication, hair transplant surgery and corticosteroid injections, Frost & Sullivan views this new
  research as a true product innovation paving the way for a wearable that could help attend one's baldness condition. However, given most of the
  commercial hair loss home treatment devices are expensive (generally ranging from \$4,000 to \$15,000), it will be interesting to see how this product is
  commercially priced, if and when it comes to the market.
- Target End-User: Healthcare Consumers, Hair Treatment Clinics

### Qualcomm's new chip will make your next Wear OS smartwatch last longer-September 10, 2018 (1/2)



#### ANALYST TAKE:

- Synopsis: Qualcomm has revealed its new smartwatch platform, the Snapdragon Wear 3100, which will power the next wave of Wear OS devices. The 3100 is a hybrid platform of old technology and new, with the added new co-processor helping eke out more power. Qualcomm says that the co-processor will reduce power consumption by 20 times compared to the main processor.
- Industry Need: When it comes to wearables technologies and healthcare, strong customer demand and surging sales are only part of the story. The other
  part is the highly volatile marketplace, where due to intense competition there is a revolving door of company entries and exits. One of the chief issues
  limiting consumer stickiness is around the poor battery life for a majority of the wearable devices in the market today. Additionally, any emerging feature or
  attributes such as always on, multi-functional, interoperability, processing 3rd party apps, and real-time applications are highly dependent on the battery
  performance which calls for innovation around processor efficiency and alternate power sources.

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# Could We Soon Be Using A Wearable Device For Regrowing Hair – September 10, 2018 (1/2)

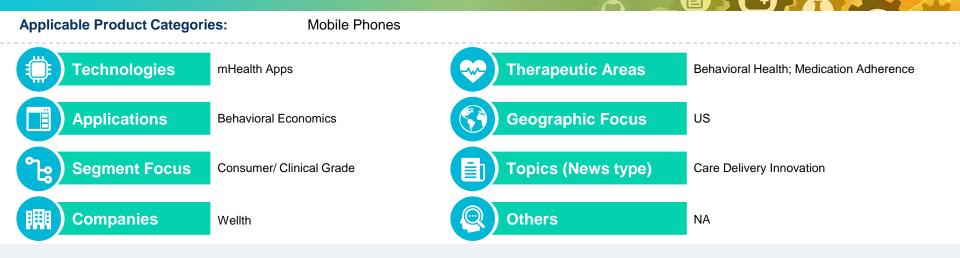
- Value Proposition: To stay competitive, Qualcomm, one of the leading chip makers for wearable devices, is expected to release the new version of its smartwatch chipset called Qualcomm 3100. The next-generation smartwatch chipset from Qualcomm will be built from the ground up with a focus on smartwatches to ensure an optimal experience for smartwatch users. The new processor platform is expected to come with 4-12 hours more battery life. Some of the additional features with upcoming Qualcomm 3100 processor are expected to enable smartwatch OEMs to integrate more energy-intensive fitness features such as;
  - Three "personalized" modes tailored for different use cases such as personalized sports experiences mode that keeps GPS and heart rate tracking going for the duration of the workout.
  - The Snapdragon 3100 is also reported to be used for all wearable devices including Google's next generation augmented reality glasses.
- The new 3100 chip comes in three varieties for manufacturers to choose from. One is designed for Bluetooth and Wi-Fi tethered smartwatches, one for watches reliant on GPS, and another for 4G LTE devices. Qualcomm is already working with a handful of manufacturers to get the 3100 chip on wrists including the Fossil Group, Montblanc and Louis Vuitton. Montblanc is the first to show off a 3100-powered smartwatch, the <u>Montblanc Summit 2</u>, which it's pushing as a versatile, unisex smartwatch for adventurers and city slickers alike.
- Frost & Sullivan views Qualcomm's 3100 new smartwatch platform as a welcome update/improvement, but not enough to create a leapfrog impact. A
  majority of the focus has been around power efficiency, rather than other performance gains. Given the forward looking nature of the announcement, it is
  difficult to assess how much better all of this will be however, if Qualcomm manages to walk the talk on Snapdragon 3100 energy efficiency promises, it
  will create a quick win, generating concern for competing chip makers in the wearable space.
- Target End-User: Health Wearable OEMs (e.g. Smartwatch and smart glasses)

#### WEBLINK: https://bit.ly/2QuWrBd



### **Mobile Phones/ mHealth**

### Behavioral economics startup Wellth lands \$5.1M – September 13, 2018



#### ANALYST TAKE:

- Synopsis: Behavioral economics start-up, Wellth, that works with payers and risk-based providers to give patients financial incentives for medication adherence completes Series A financing.
- Frost & Sullivan believes that behavioral economics, a culmination of behavioral health, healthcare gamification as well as financial incentivization, is an
  emerging concept wherein patients are incentivized, mostly financially, to adhere to treatment regimens. This is fast emerging as a tool for insurers, payers
  and providers to evaluate and devise drug and treatment adherence strategies. The approach, gaining prominence in a value based reimbursement
  context, has seen health systems get into innovative pilots for chronic disease programs wherein patients earn monetary benefits often as high as \$50 per
  month for treatment and drug adherence.

### AliveCor's Al for noninvasive blood potassium screening snags Breakthrough Device designation from FDA – September 12, 2018 (1/2)



#### ANALYST TAKE:

**Synopsis:** AliveCor's KardiaK Software Platform, an AI enabled neural network which reads ECG data from on-body devices, has been granted Breakthrough Device designation by the FDA for enabling non-invasive diagnosis of elevated blood potassium levels, a condition known as hyperkalemia that affects the kidneys.

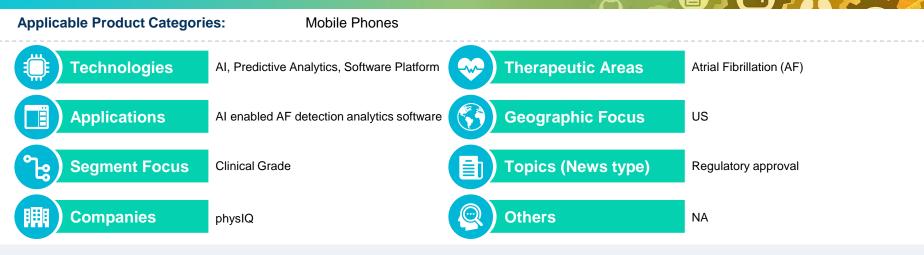
#### Industry Need:

- Hyperkalemia, a condition affecting 1.57% of US population, is one of the most important electrolyte abnormalities with potential to cause fatal cardiac arrhythmia. The prevalence increases to 6.35% in patients with chronic kidney diseases (CKD), heart failure, hypertension and diabetes. The incidence of hyperkalemia has been reported to increase since 2010.
- Due to heightened risks of cardiac arrests, patients with CKD and diabetes, are required to be screened for hyperkalemia for a timely intervention. However, current methods require blood serum analysis which is time consuming and often misleading due to hemolysis of blood cells in drawn blood samples, thus leading to faulty potassium readings.

#### Value Proposition:

- AliveCor's KardiaK software is trained to read ECG data for elevated levels of blood potassium and could be performed in a home setting if the user owns a on-body ECG device.
- The FDA Breakthrough Device status, while not a clearance in itself, is a big leap forward for accelerated clearance by the FDA. The platform demonstrated
  a success rate or area under the receiver operating characteristic curve (AUC) of 0.88-0.89 against a set of 2 million ECGs and 4 million serum potassium
  values.
- Frost & Sullivan believes that while treatment for hyperkalemia is effective and readily available, accurate and non-invasive diagnosis of hyperkalemia is still an unmet need with the existing Gold Standard being a lab based blood test which entails the challenges of inconvenience, time loss as well as lack of accuracy. AliveCor's KardiaK platform, in addition to addressing most of these issues, has created a niche for itself in this space by being the only provider of home based assessment of elevated blood potassium levels. We expect the platform to receive FDA clearance very soon, post which it could be a synergistic enabler of AliveCor's current portfolio of clinical grade offerings such as KardiaBand and KardiaMobile. In addition, the interoperability of KardiaK platform with other ECG devices will further enhance adoption and care outcomes.
- Target End-User: CKD, hypertension, diabetes and heart failure patients

### physIQ gets FDA nod for a-fib analytics system – September 12, 2018 (



#### ANALYST TAKE:

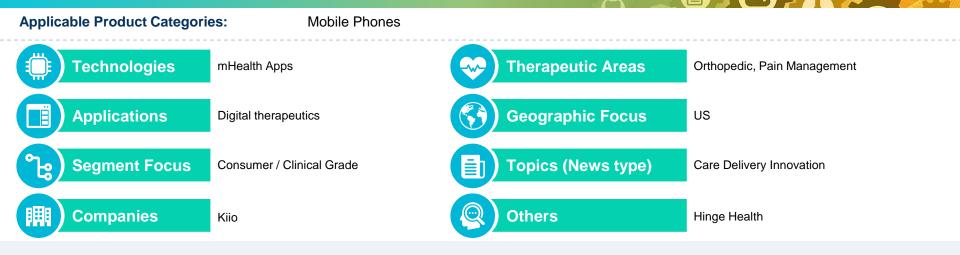
**Synopsis:** physIQ got FDA nod for its atrial fibrillation detection analytics engine, intended to be used in both a patient care setting and in clinical trials. **Industry Need:** 

- A network of connected devices and cloud based data management systems have been generating huge amounts of valuable patient data. However, effective analysis to generate actionable insights on patient condition and population health has been a high priority area for US health systems so as to optimize care delivery.
- Moreover, advanced biosensor based health monitoring and AI enabled risk assessment has assumed greater importance for post-acute patients wherein clinicians have been able to track progress and take timely preventive action so as to reduce readmission rates.

#### Value Proposition:

- PhysIQ's latest AF detection platform works in tandem with its pre-existing physiology analytics system, which is an early warning system analyzing the
  patient's physiological data, including blood pressure, heart rate, oximetry, and respiration rate to create a personalized risk based model for each patient
  so that the offering can compare a user's data to their own baseline.
- The AF platforms will be used in conjunction with its wearable biosensor pinpointIQ for continuous monitoring and AF related risk assessment. In addition, the company's accelerateIQ platform, is a clinical trials platform which can collect data from several biosensors and stream data to the physIQ cloud platform to glean population level insights as well as quantification of impacts of clinical trials on patient health.
- The company has partnered with health systems such as the Dept of Veterans Affairs to demonstrate the impact of wearable biosensor enabled continuous data aggregation and the subsequent AI based predictive insights generation in detection of vital signs anomalies in heart patients. physIQ has also partnered with VitalConnect and Haga Teaching Hospital in Netherlands for a cancer study funded by Johnson & Johnson subsidiary Janssen Pharmaceuticals.
- Frost & Sullivan believes that physIQ tools are essential for payers and providers to effectively assess their care strategies, and to tackle reimbursement related challenges in a value based care scenario. Additionally, physIQ's partnership based approach, wherein it makes the platform available for pharma and medical device incumbents, will further enhance stakeholder interest in terms of adoption of risk-based contracting models.
- · Target End-User: Patients, clinicians, pharma, medical device, hospital networks

## Pilot of Kiio's digital back pain therapy reports improved outcomes among those who used it – September 10, 2018



#### ANALYST TAKE:

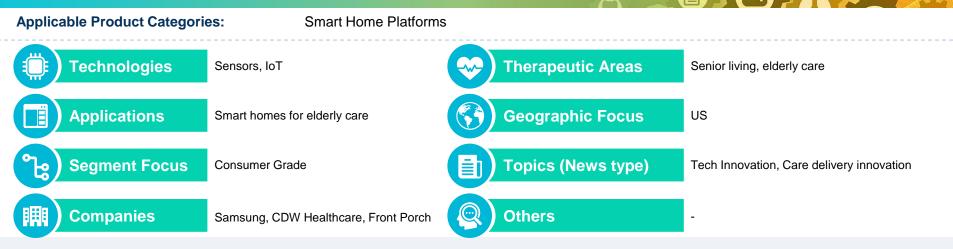
- **Synopsis:** Kiio's app based back pain therapy program, in partnership with health systems and employers has reported positive results from its 1 year pilot within Quartz Health Solutions health plan system.
- Digital therapeutics is an emerging area with a total estimated market size of \$889 million in 2017 as per the latest Frost & Sullivan study, with chronic condition management being the largest sub-segment expected to grow at a CAGR of 30.8% during 2017-23. Lower back pain is a chronic condition, accentuated by unhealthy lifestyle, affecting a significant portion of US population. App based virtual therapies, often accompanied with wearable sensors, have been an evolving digital health offering. They often involve a telehealth aspect through virtual coaching and interactive patient education, aimed at improving engagement and outcomes.



### **Smart Home Devices & Appliances**

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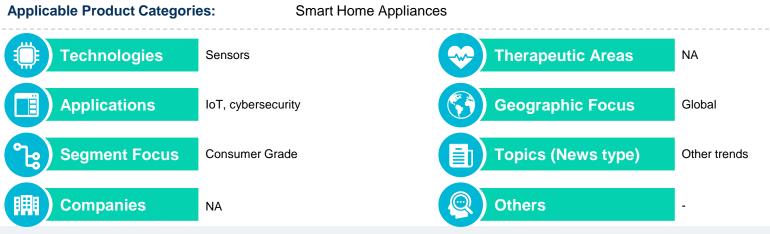
### Smart Home Technology Becomes a Must-Have in Senior Living -September 10, 2018



#### ANALYST TAKE:

- Synopsis: Panel discussion at Senior Housing News Summit in Los Angeles, on the role of smart home environments for senior living.
- Frost & Sullivan appreciates and acknowledges the efforts of Front Porch and other players who are playing a pioneering role in piloting tech, adapting it to
  their community preferences and sharing their learning along the way. A key lesson here is to acknowledge that seniors aren't tech-savvy, and to take
  things 'one step at a time' pre-configured smart home environments may not be the best way forward, but to allow seniors to test the technology first and
  then choose their preferences (this applies for smart home appliances, and voice assistants as well). However, the other aspect is the use of non-resident
  facing tech, which can provide insight in their health and wellbeing use of sensors for fall detection, or even to ensure normalcy in routine, where the data
  and insights are provided to a doctor, nurse of staff members, could be a standardized element of such smart homes [privacy issues may play a role here.]

## It's a mad, mad, mad IoT world – protecting America's power grid from common household appliances – September 10, 2018



#### ANALYST TAKE:

- Synopsis: Proliferation of IoT devices including those in smart homes has cybersecurity professionals concerned.
- Frost & Sullivan agrees with the views in the article, poorly secured IoT devices in the smart home network can result in hacking. In our opinion, such efforts could be very well used for (a) access to health information (which sells for \$50 / records vs. \$1 for SSN / credit card info), (b) breach of privacy, domestic abuse, (c) leverage collective computing prowess for mining cryptocurrency (raising electricity bills), or (d) as the article suggests, to take out power grids in a 'firesale' kind of a situation. This, in the future, could very well be possible, and being prepared today is crucial to prevent such a scenario and the consequences for vendors providing this products and services. The security would be only as strong as the weakest link: as the article highlights, Target was hacked through their HVAC system! Therefore, standards and protocols built by a consortium, such as the Personal Connected Health Alliance (of which Continua Health Alliance was a founding member) will be crucial to ensure cybersecurity for vendors, providers and customers.

#### WEBLINK: https://bit.ly/2NJrPgM

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Several 'Smart Homes for Aging-in-Place' initiatives are coming up across Europe and the US, and have been covered in previous newsletters. Since the theme remains the same, additional articles have been added here:

News Title	Region	Date	Link
'Smart homes' for seniors, disabled adults unveiled in Clarksville	US	Sept 5, 2018	https://leafne.ws/2pcWg1n