

Healthcare Market Updates



OHK		
AAPL	+2.35	
PRTG	-0.14	
AMZN	-0.73	
TSLA	+1.08	
AVGO	-0.87	-3.0%
SIRI	-0.65	

Weekly Newsletter
Issue 24
19th October, 2018

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









Wearables

Apple Donating 1000 Watches for Binge Eating Study is a Part of a Larger Health Push – 16 October, 2018 (1/2)

Applicable Product Categories:

Wearables

 Technologies	Wearable (smartwatch)	 Therapeutic Areas	Lifestyle/Food Habits monitoring for Chronic Disease Management
 Applications	Patient monitoring, Self-health management	 Geographic Focus	US
 Segment Focus	Consumer/Clinical Grade	 Topics (News type)	Business Model Innovation; Competitive Intelligence
 Companies	Apple Inc.	 Others	NA

ANALYST TAKE:

- **Synopsis:** Apple announced donation of 1000 Apple Watches for an eating disorders research study. The research is undertaken by the University of North Carolina (UNC) that will record the data produced by the Apple Watch units and then analyse to understand root causes of the disease (i.e. attempts to find out whether binge eating is due to biological and behavioral signature).
- **Industry Need:** Bulimia is a potentially life-threatening eating disorder, in which people tend to binge eat. Subsequently, they then take steps to avoid weight gain, perhaps as a counter measure for all the food they have eaten—this includes forced vomiting, excessive exercising or fasting for inconsistent periods of time. According to the National Association of Anorexia Nervosa and Associated Disorders, as many as 30 million people in the United States alone suffer from an eating disorder. According to researchers, as many as 10 million cases of Bulimia Nervosa are diagnosed just in India every year. Frost & Sullivan believes, such disorders that require periodic monitoring of food habit risk factors provide a white space opportunity for wearable OEMs against other crowded healthcare applications.









Apple Donating 1000 Watches for Binge Eating Study is a Part of a Larger Health Push – 16 October, 2018 (2/2)

- **Value Proposition:** As part of this collaboration, the medical school of UNC is preparing to undertake a study called Binge Eating Genetics INitiative (BEGIN), in which researchers will observe people with binge eating disorder (also known as Bulimia Nervosa) who often eat large amounts of food uncontrollably in a small period of time. According to a report by CNBC, those who follow with compensatory behavior like purging or excessive exercise are typically diagnosed with bulimia nervosa.
- **Study Design:** For this study, Cynthia Bulik, Founding Director of the Center of Excellence for Eating Disorders at UNC and one of the researchers behind BEGIN, have invited 1,000 participants, ages 18 or older, who have experience with either binge eating disorder or bulimia nervosa and own an iPhone (model 5 or newer). Once enrolled, the participants will be required to sign up with a mobile app called Recovery Record, which is reportedly designed to help users log their thoughts and feelings in a digital format, and share that information with their doctor ahead of a session. Each participant will be wearing an Apple Watch during the 30 day period, so that researchers can monitor the heart rate to understand any deviations or noticeable trends during the time of binge eating. Apart from the Apple Watches, the participants will also get free saliva and microbiome collection kits to send samples back to the researchers.
- Frost & Sullivan views this a part of Apple's on-going academic collaboration with leading medical institutions for exploring medically meaningful novel use cases of the Apple Watch. For example, early this year, Apple announced that patients of NYU Langone Health, Stanford Medicine and 40 other health systems in the US, representing hundreds of hospitals and clinics across the country, could now view their medical records on their iPhones.
- Frost & Sullivan also believes, as care for lifestyle-driven chronic diseases expands in scope, prevention and recovery are becoming the new focus areas, apart from diagnosis and treatment. Medical experts agree that most chronic health conditions are largely preventable by employing sustainable behavior modification and wellness programs around healthy food habits attuned to individuals at risk of developing these chronic diseases. Despite the abundance of smart gadgets and wearable devices, their primary focus is vastly limited toward monitoring physical activities and biometrics; however, most of these solutions fail to solve the other half of the puzzle related to critical diet or nutrition factors.
- As wearables continue to lure consumers, and medical institutions with meaningful healthcare applications, Frost & Sullivan recognizes Apple Watch's use case positioning strategy for BEGIN disorders. The addition of the Apple Watch to the BEGIN study is just the latest push to provide better understanding about the biological and behavioral signature associated with binge-eating disorder and Bulimia Nervosa that affect millions of people. The research team at UNC anticipates that results from this study could ultimately change the course care for BEGIN episodes.
- **Target End-User:** Pharma, Payers, Consumers

WEBLINK: <https://bit.ly/2NHMdLj>

Triple W Launches DFree, First Wearable Device for Incontinence – 16 October, 2018 (1/2)

Applicable Product Categories: Wearable

 Technologies	Wearable (Device + App)	 Therapeutic Areas	Urinary Incontinence
 Applications	Assisted Living for Incontinence	 Geographic Focus	Global
 Segment Focus	Consumer/Clinical Grade	 Topics (News type)	Business Model Innovation; Competitive Intelligence
 Companies	Triple W	 Others	NA

ANALYST TAKE:

- **Synopsis:** San Diego-based Triple W has launched a new wearable connected health monitor in the United States, focused on urinary incontinence. The sensor, called DFree, uses an ultrasound sensor to monitor changes in bladder size. Then proprietary algorithms translate that data into information about when a user should head to the bathroom.
- **Industry Need:** Incontinence is a widespread but underreported problem, because of the social stigmas involved. The NIH estimates it affects 500 million people worldwide and US retail sales of adult diapers totalled \$2 billion in 2016. That market is only growing as baby boomers age. Urinary incontinence occurs when there is loss of bladder control. It's common among seniors, especially women. It may be caused by weak or overactive bladder muscles, weak pelvic floor muscles, or damage to nerves that control the bladder from diseases such as multiple sclerosis, diabetes or Parkinson's disease. Other causes of incontinence include blockage from an enlarged prostate in men, injury or damage to nerves and muscles from surgery.

Triple W Launches DFree, First Wearable Device for Incontinence – 16 October, 2018 (2/2)









- **Value Proposition:** Triple W's connected health device Dfree comes as a convenient and cost-effective alternative to disposable diapers or pads and medications for seniors, children, and disabled people with bladder control issues (also known as urinary incontinence). Dfree helps individuals with incontinence with freedom to live an active lifestyle and improve quality of life.
- **How DFree Works?** The receiver weighs 2.5 ounces and has a rechargeable battery that lasts about 24 hours. The device may be discreetly clipped on your belt or clothing while the non-invasive ultrasound sensor is secured to the lower abdomen with medical tape. The sensor uses non-harmful ultrasound technology to monitor the change in bladder size and predicts urination timing using a patented algorithm. The device sends data to an iOS app (Android is coming soon, the company says) which can be set to notify the wearer when their bladder is, for instance, 65%, 70%, and 85% full. The user can then discreetly get up to go to the bathroom.
- **Commercialization:** As per the company report, DFree has been used in over 500 senior care facilities in Japan and Europe since 2017. It is now available on the DFree website for \$499.99 (MSRP). Triple W is offering a 15% discount on the purchase of DFree for attendees during Medtrade (October 15-17, 2018). Triple W is also offering a Referral Program for anyone who makes a purchase using a unique DFree code. The referee will receive a \$50 check once their referred friend/family completes a purchase using their unique code. The referred buyer will also receive a 15% discount towards the purchase.
- Despite the industry need and associated commercial opportunity, Frost & Sullivan finds limited number of wearable/digital health companies currently operational in this space (such as Brightly by Lir Scientific and PeriCoach for female urinary incontinence). Given this, Frost & Sullivan finds Triple W's market position for Dfree wearable device as a much needed digital solution for a widespread but underreported condition such as incontinence. Frost & Sullivan also finds Dfree's aesthetic design intriguing, that help individuals with incontinence improve quality of life and enable independence, as well as help reduce the burden for caregivers, and the associated social stigma.
- **Target End-User:** Payers / Health Systems, Aged Care, Femtech, Consumers

WEBLINK: <https://bit.ly/2QYSZyd>

Autism & ADHD Parents In Australia Rejoice With Revolutionary TouchPoints™ Shipping Locally – 16 October, 2018 (1/2)

Applicable Product Categories:

Wearable

 Technologies	Wearable (smartwatch)	 Therapeutic Areas	Childhood Anxiety, Autism & ADHD
 Applications	Patient monitoring, Self-health management	 Geographic Focus	US/Global
 Segment Focus	Consumer/Clinical Grade	 Topics (News type)	Business Model Innovation; Competitive Intelligence
 Companies	TouchPoints	 Others	NA

ANALYST TAKE:

- **Synopsis:** TouchPoints™ is a wearable device that claims to provide immediate relief from stress and anxiety in kids and adults with Autism, ADHD and helps improve productivity and sleep.
- **Industry Need:** Research suggests that anxiety disorders are the most common childhood-onset psychiatric disorders – affecting over 25% of teenagers who struggle with mild to moderate anxiety. If untreated, anxiety disorders tend to be chronic with waxing and waning symptoms. For example as per WHO, depression and anxiety disorders fall into the top 5 causes of overall disease burden among children and adolescents (as measured by disability-adjusted life years) especially in the developed part of the world.

Autism & ADHD Parents In Australia Rejoice With Revolutionary TouchPoints™ Shipping Locally – 16 October, 2018 (2/2)

- **Value Proposition:** TouchPoints are twin neuroscientific wearables that were designed to provide fast relief from stress at the push of a button. The company claims that, TouchPoints which is a 100% non-invasive neuroscience based device can reduce the stress level by 70% in just a matter of 30 seconds. TouchPoints use BLAST (Bi-Lateral Alternating Stimulation Tactile) technology in the form of gentle vibrations to alter your body's natural stress response and keep you in a calm state of mind. TouchPoints™ Original model of device comes in the design of a two wrist band/watch and is app-controlled to provide highly customizable therapies with up to six pre-settings (such as; calm, focus, sleep, performance, anger, and cravings). TouchPoints devices comes in the form of value bundles (ranging from 2 to 8 device bundles). The average price for a 2 Original device bundle is priced at \$249.99.
- **Commercialization Strategy:**
 - TouchPoints had recently partnered with the Ashanti singing band for superheroes, and Indiegogo, to raise childhood anxiety awareness in the Boys and Girls Clubs across America.
 - Apart for the American region, TouchPoints™ is now available in Australia across select official stores.
- Given that, onset of most anxiety disorders occurs during childhood, adolescence or early adulthood, Frost & Sullivan finds TouchPoints' market positioning thoughtful compared to other competing products that generally miss meaningful healthcare use cases by targeting the broader mental health space.
- Additionally, recent Anxiety disorders in children (up to 12 years old) and adolescents (13 to 18 years old) are associated with educational underachievement and co-occurring psychiatric conditions, as well as functional impairments that can extend into adulthood. Entailing this, Frost & Sullivan finds TouchPoints recent marketing campaign with the Ashanti singing band intriguing as they aim to bring awareness around children facing disabilities and diseases through the power of music. The company also reports that apart from their core target market (Childhood Anxiety, Autism & ADHD), it is also finding use among executives and professionals who complain of mental stress arising out of a busy and stressful lifestyle.
- **Target End-User:** Health Systems, Consumers, Employee Health Programs

WEBLINK: <https://bit.ly/2OulxD8>; <https://bit.ly/2Ex8Q65>











Mobile Phones/ mHealth

Apple hopes the Apple Watch can help patients recover faster from knee and hip replacements – October 15, 2018 (1/2)

Applicable Product Categories:

Mobile Phones

 Technologies	mHealth app	 Therapeutic Areas	Orthopedic Surgery
 Applications	mHealth app and smart watch for orthopedic rehabilitation	 Geographic Focus	Global
 Segment Focus	Clinical Grade	 Topics (News type)	M&A/ Collaborations/ Investments
 Companies	Apple; Zimmer Biomet	 Others	NA

ANALYST TAKE:

Synopsis: Apple and Zimmer Biomet have announced partnership for a new clinical study and Apple Watch app focusing on pre and post operative care management of knee and hip replacement patients.

Industry Need:

- Orthopedic surgeries such as a knee, hip and shoulder implant or a joint replacement, are expected to increase at a healthy CAGR across the ageing nations such as the US, Japan and the UK. However, pre and post care coordination for orthopedic procedures is an emerging challenge owing to evolution of same day surgeries, leading to greater burden of post-acute care coordination of the patient's entire 90-day episode of care.
- Additionally, lack of technological advancements in orthopedic implant sensors, has further added to difficulties in remote monitoring and care coordination in terms of improvements in mobility, range of motion and infection risks of implants, thereby increasing care costs and sub-optimal care outcomes.

Apple hopes the Apple Watch can help patients recover faster from knee and hip replacements – October 15, 2018 (1/2)

Value Proposition:









- The Apple and Zimmer Biomet partnership entails enrolling 10,000 US based knee and hip implant patients in a new clinical trial involving the Apple Watch and the specialized app (launched as part of this partnership) known as mymobility.
- The app includes educational tools, workout videos as well as a way to contact the care team to assist patients throughout their surgery experience. The Apple watch, on the other hand, will allow for activity and heart rate tracking that can be shared with the care team. Each of these features is intended to help researchers and orthopedic practitioners better understand the factors that impact surgery recovery.
- Frost & Sullivan finds this in line with the current trend of Medtech incumbents developing therapeutic area specific platforms of care to take care of patients across the continuum. J&J launched a surgery focused platform called Health Partner last December wherein it guides the patients across the entire surgical journey and prepares them mentally, physically and emotionally. While companies are developing their individualized care platforms today, eventually we foresee that these will break the organization level siloes to create integrated care platforms for a specific therapeutic area. Of course, medtech can't do it alone and they will need to partner with IT and tech companies to leverage their platform and data capabilities. The current partnership between Zimmer and Apple is a case at hand. In line with the broader themes of patient centricity and newer business model innovations, companies are now evolving their strategies from a product+service centric approach towards a "Insights as a Service" or a "Platform as a service" approach. Eventually its all going to be differentiated through how much data and analytical tools companies could leverage to come up with actionable insights on a particular area of focus.
- **Target End-User:** Hospitals; Primary Care Centers; Orthopedic rehabilitation centers; Patients

WEBLINK: <https://cnb.cx/2QShqO2>

Tyto Care secures CE Mark, paving the way for Europe rollout – October 16, 2018 (1/2)

Applicable Product Categories:

Mobile Phones

 Technologies	mHealth; Telehealth; Connected Devices	 Therapeutic Areas	Home Based Primary Care
 Applications	Connected home based devices enabling telehealth	 Geographic Focus	Europe
 Segment Focus	Clinical Grade	 Topics (News type)	Regulatory
 Companies	TytoCare	 Others	NA

ANALYST TAKE:

Synopsis: Netanya, Israel based TytoCare, a company which offers a comprehensive suite of home based primary health examination and telehealth tools has secured CE Mark approval, allowing it to expand its offerings into Europe.

Industry Need:

- The telehealth and telecare market in Europe is in a growth phase with growth rates expected to be consistent for the next two to three years, following which it is expected to show a steady increase depending on the establishment of infrastructure, reimbursement guidelines, and commercialization of pilot projects.
- A rising ageing population and need for chronic disease management have given impetus to telehealth and telecare adoption. Initiatives by the government and regional healthcare authorities to convert major pilot projects to large-scale commercial deployments will contribute to the adoption of telehealth and telecare across Europe; this will be further augmented by Europe's eHealth policies and digital agenda.

Tyto Care secures CE Mark, paving the way for Europe rollout – October 16, 2018 (2/2)

Value Proposition:









- TytoCare enables effective remote consultations with a suite of connected devices available to the patient at home which are generally required for in-person physician visit: a connected otoscope, stethoscope, basal thermometer and digital camera.
- TytoCare enables home based telemedicine, remote diagnostics and monitoring of a variety of vitals for conditions related to a variety of body organs. It also offers heart exams, which enables clinicians to remotely hear and assess heart sounds. The company's ability of generating digital prescriptions which could be shared by the physician directly to the pharmacy for pick up and medication management further adds value to patients in terms of ease of access and home based care.
- The company offers B2B2C service model via health systems, employers and other telemedicine companies and eventually plans to sell a direct-to-consumer offering called TytoHome.
- Frost & Sullivan believes that, the company's CE mark approval is a major milestone, given the high potential of the European market for telehealth as well as its level of maturity in terms of the required infrastructure and adoption by the healthcare systems. The success of companies such as Babylon Health is a good indicator of the appetite for such tools in the European market, which has traditionally struggled to keep up with the increasing demand for primary care services owing to a ageing population and the rise in chronic disease burden.
- **Target End-User:** Hospitals; Primary Care Centers; GP Clinics; Patients

WEBLINK: <https://bit.ly/2Ahv0EV>

SilverSneakers Introduces SilverSneakers GO, Innovative Mobile Fitness App Designed Exclusively for Seniors — October 17, 2018

Applicable Product Categories:

Mobile Phones

 Technologies	mHealth app	 Therapeutic Areas	Healthy Ageing
 Applications	mHealth app for healthy ageing	 Geographic Focus	US
 Segment Focus	Clinical/ Consumer Grade	 Topics (News type)	Care Delivery Innovation
 Companies	SilverSneakers	 Others	NA

ANALYST TAKE:

- **Synopsis:** SilverSneakers, a community fitness program for elderly population in the US, SilverSneakers GO™, a mobile fitness app that claims to differentiate itself based on the capability to modify the exercise difficulty based on the elderly individual's ability to complete a suggested exercise.
- Frost & Sullivan research finds that the aged care and health ageing market is a highly crowded place with a number of, now, legacy technologies, such as mHealth apps, smartwatches, and wearables as well as some newer technologies such as AI enabled interactive robots, all vying for their space in an attractive segment driven by the shifting focus from “sick care” to “healthcare”. A range of businesses such as technology companies, real estate, pharma/ medtech, retail as well as manpower services have entered the market in varying degrees tapping a specific need in aged care such as utilities, geriatric medicine, or assisted living. Amidst such as fiercely competitive marketplace, it is imperative to clearly and uniquely define the value proposition of a newly launched product or service, thereby enabling a distinctive recall factor. With a distinct focus on seniors in the highly crowded fitness app market, and targeting the attractive senior care market, SilverSneakers may achieve that differentiation.

WEBLINK: <https://prn.to/2Ahe9Cs>








Smart Home Devices & Appliances

This Device Gives Users the Power to Program Their Own Smart Home – October 14, 2018

Applicable Product Categories:

Smart Home Devices

 Technologies	IoT	 Therapeutic Areas	NA
 Applications	AI, Home Automation	 Geographic Focus	Global
 Segment Focus	Consumer Grade	 Topics (News type)	Technology Innovation
 Companies	Guiott	 Others	-

ANALYST TAKE:



- **Synopsis:** The CM3-Home is a Raspberry Pi Compute Module 3 designed to give anyone the power to automate systems within their homes.
- For those who love to tinker with software and systems (or the DIYers) this is a very handy device, allowing them much more ‘control’ on their smart home devices and systems. Frost notes that the target population for this device is considerably small, in the current state. However, we also note that startups or other companies willing to leverage this control over devices of multiple brands (that don’t necessarily talk to each other directly) is a possibility. In the healthcare space, for an aging-in-place scenario, a remotely located caregiver may be able to control the home environment in case the resident senior cannot do so themselves. The opportunity potential of such a device are wide-ranging, however building the right applications around it, with the right interface (if required) will be crucial for making optimum use.

WEBLINK: <https://bit.ly/2OulK8n>

A DIY Smart-Home Built with Smartians – October 15, 2018

Applicable Product Categories:

Smart Home Devices

 Technologies	IoT	 Therapeutic Areas	NA
 Applications	AI, Home Automation	 Geographic Focus	Netherlands / EU
 Segment Focus	Consumer Grade	 Topics (News type)	Technology Innovation
 Companies	FROLIC Studio	 Others	-

ANALYST TAKE:

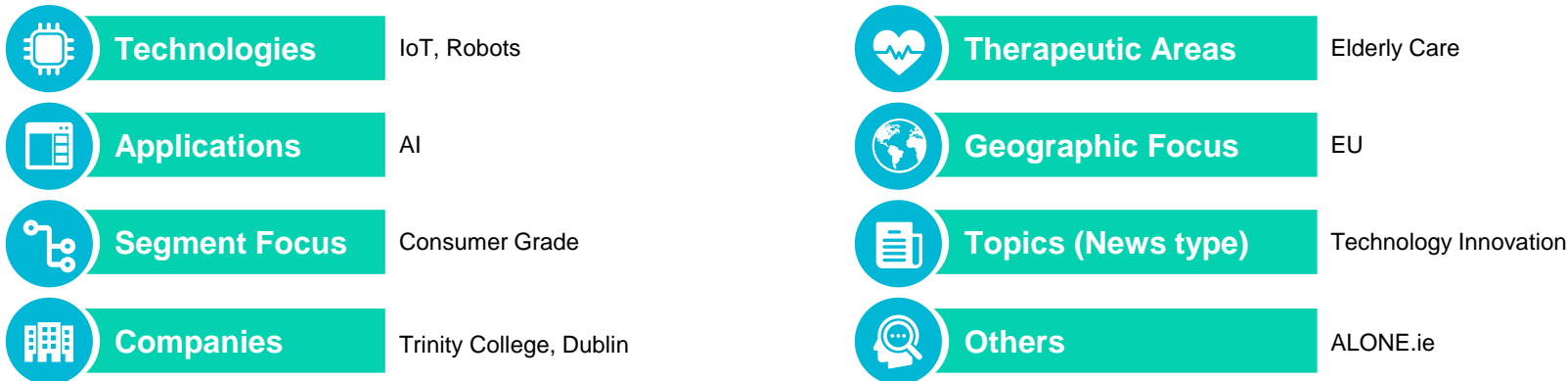
- **Synopsis:** Smartian products make non-smart / connected things smart: the tools—which press, turn and do whatever else you need—lend a DIY, cloud-controlled upgrade to just about anything. [see pictures in article for clarity.]
- This is an extremely smart step (pun intended) – to make non-smart things smart, which expands the target market to even those consumers who don't wish to replace their existing devices or systems. Enabling them to go smart, and by means which are fairly easy to adapt, also allows DIYers to do more, without worrying about brand specific apps or protocols, enabling them to build customized automation processes to suit their needs. While it isn't clear whether physical use of the home devices is still possible (i.e. after installing smartians automation tools), having that functionality could allow non-tech-savvy seniors to operate the devices manually, while their caregivers could operate them virtually, and possibly remotely too.

WEBLINK: <https://bit.ly/2ymOxCG>

Stevie the Robot Wants to Help the Elderly – October 14, 2018

Applicable Product Categories:

Robots



ANALYST TAKE:









- **Synopsis:** In yet another news from the Maker Faire in Rome, robotics engineers from Trinity College Dublin, have designed Stevie the robot, with some human-like features, for giving company to the elderly.
- Frost notes that Stevie is a mobile robot, one of the very few designed for elderly care (others like Mabu or ElliQ are not mobile). Given its technological complexity, its cost will be high, and therefore its positioning for nursing homes and assisted care facilities makes sense (instead of individual homes). Its ability for social interaction (similar to ElliQ), allows it to play simple games and have basic conversations with seniors to eliminate boredom. But in Frost's view, the most important feature that Stevie has, is the ability to interact with and control smart home technology – appliances and things such as the thermostat. While too early for commercialization, some nursing homes around the world are already buying robots – such as those from Yujin Robots, for example.

WEBLINK: <https://bit.ly/2EmyFFz>

LG's new smart sofa concept recognizes whoever sits on it – October 15, 2018

Applicable Product Categories:

Smart Home Devices

 Technologies	IoT	 Therapeutic Areas	Chronic Care, Obesity
 Applications	Smart Furniture	 Geographic Focus	Global
 Segment Focus	Consumer Grade	 Topics (News type)	Technology Innovation, Competitive Intelligence
 Companies	LG, Natuzzi	 Others	-

ANALYST TAKE:









- **Synopsis:** LG has teamed up with Natuzzi, Italy's largest furniture company, to produce a concept demonstrating what the smart and connected sofa of the future could look like in a home. The Colosseo sofa is said to recognize who sits on it, then can automatically adjust its position to suit that person's preferences. Via Google Home assistant, it can also talk to other smart home devices.
- Frost & Sullivan believes that this concept prototype could become a standard part of smart homes for healthcare applications, in about a decade from now. While the current focus for LG is customer convenience, the whole concept could be flipped around to also make residents more active (as opposed to being 'couch potatoes'). Tracking length of time seated, posture and comparing with other fitness activity data, smart homes can coax or nudge residents to be more active, helping prevent obesity and development of chronic conditions, helping promote overall wellness.

WEBLINK: <https://bit.ly/2PGmpkH>

Cedars-Sinai accelerator helps launch 8 healthcare startups— October 12, 2018

Applicable Product Categories:

Virtual Assistants / Bixby

 Technologies	IoT, Voice	 Therapeutic Areas	Chronic Heart Patients
 Applications	Patient engagement	 Geographic Focus	US
 Segment Focus	Clinical Grade	 Topics (News type)	Technology Innovation, Competitive Intelligence
 Companies	CardioCube, Sopris Health	 Others	-

ANALYST TAKE:

- **Synopsis:** Eight startups graduated from the Cedars Sinai accelerator, of which two are important to focus on –CardioCube and Sopris Health.
- CardioCube – Having contracts with Cedars Sinai and Johns Hopkins, this voice technology based product allows chronic heart patients to record their symptoms from home, receive guidance and education, and to share symptoms with their cardiologist too. Voice is an excellent interface for such use cases, and with smart speakers becoming widely available, allow a large number of patients to access this tool.
- Sopris Health – Employing NLP and machine learning, the tool captures doctor-patient interactions, and translates to clinical notes. From a home perspective, having this tool available for telemedicine format, and also making available the clinical notes and medication guidance and treatment regimen available in detail (not just the prescription) can be very valuable for patients and caregivers.

WEBLINK: <https://bit.ly/2yoTR8N>

Other Interesting Articles

When available, other interesting articles will be covered here in short.

News Title	Link	Remarks
The average Aussie home has 27 connected devices, here's why that's growing	https://bit.ly/2J67ZYy	There are 4 drivers – security, utility cost savings, comfort and control. Australian homes have 27 connected devices that include smartphones, tablets, watches, TVs, fitbits and even fridges.
Glitch in Yale's smart security system sees Brits 'locked out' of homes	https://bit.ly/2Ov2QPz	As discussed earlier too, 'smart' technology needs to have alternatives when the tech breaks-down. Imagine this happening with healthcare applications – such products would never be adopted, or likely get regulatory approvals.