FROST & SULLIVAN

Healthcare Market Updates

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Wearables

Wearable Cardiac Monitor Approved in S. Korea Under ICT Regulatory Sandbox – March 25, 2019

Applicable Product Categories: Wearables

Technologies — Wearable (Smartwatch)

Therapeutic Areas — Cardiac Health Monitoring (e,g. ECG)

Applications — Remote Patient Monitoring

Geographic Focus — Global

Segment Focus — Clinical Grade

Topics (News type) — Competitive Intelligence

Companies — HUINNO Inc.

Others — NA

ANALYST TAKE:

Synopsis: A wearable to measure electrocardiogram (ECG) has received the green light from local (Korean) health authorities, the watch's manufacturer said Monday. The approval is the first since the government adopted the so-called regulatory sandbox -- a mechanism for developing regulations that keep up with the fast pace of innovation -- in the ICT sector.

Value Proposition: HUINNO Inc. said its MEMO Watch product became the country's first wearable medical device certified by the Ministry of Food and Drug Safety. The company first developed wearable ECG monitoring system in 2015, before the launch of Apple 4 by US tech giant Apple Inc. The product, however, could not be sold there mainly because it was tied down by regulations. As per the company, patients wearing the device will be able to send ECG data at any time of day to healthcare providers and receive medical counselling about their conditions.

Frost & Sullivan views this as an on-going trend of favourable regulatory and reimbursement sentiments by global healthcare authorities to promote clinically relevant digital health applications across care delivery models beyond physical medicine to include behavioral health, digital wellness therapies, dentistry, nutrition, and prescription management. Given the competitive landscape for medical-grade ECG wearables, it will interesting to look for the pricing point of the MEMO watch.

End-Users: Hospital, Cardiac Rehab, Consumers, Clinical Trials

WEBLINK: https://bit.ly/2FJu1QT

ECG app and irregular rhythm notification on Apple Watch available today across Europe and Hong Kong – March 27, 2019 (1/2)

Applicable Product Categories: Wearables

Technologies	Wearable (Device + App)	**Therapeutic Areas**	Cardiac Health Monitoring (e,g. ECG)
Applications	Remote Patient Monitoring	**Geographic Focus**	Global
Segment Focus	Clinical Grade	**Topics (News type)**	Competitive Intelligence
Companies	Apple	**Others**	NA

ANALYST TAKE:

Synopsis: After its successful debut in the US this past September, the ECG app on the Apple Watch Series 4 arrived Thursday in Hong Kong and 19 European countries, including France, Germany, Italy, Spain and the United Kingdom. The new regions are part of the watch OS 5.2 update.

Industry Challenge: Based on industry estimates, 7.3 million people die of CVD, particularly heart attacks and strokes every year globally. Among heart diseases Atrial fibrillation (Afib) is the most common heart rhythm abnormality. Afib can be reduced with treatment, but often atrial fibrillation (AF) has silent symptoms and goes undetected. If left untreated, AFib is one of the leading conditions that can result in stroke, the second most common cause of death around the world. The ECG app and irregular rhythm notification feature on Apple Watch can alert users to signs of Afib to avoid critical health risks.

Value Proposition:

- In addition to receiving De Novo clearance in the US from the FDA, the ECG app and irregular rhythm notification in Apple Watch Series 4 are now CE marked and cleared in the European Economic Area.

- Apple Watch Series 4, is launched as a direct-to-consumer product that enables customers in Hong Kong and 19 European countries, including France, Germany, Italy, Spain and the United Kingdom to take an ECG right from their wrist. The company claims that, the ECG app has the ability to take an ECG readings in 30 seconds and detect warning signs like irregular heart rhythm or atrial fibrillation.

- As part of the free watchOS 5.2 software update, the ECG app can capture heart rhythm on demand in a moment when users experience symptoms such as a rapid or skipped heart beat and help provide clinically important data to physicians. The irregular rhythm notification feature on Apple Watch occasionally checks heart rhythm in the background and sends a notification if an irregular heart rhythm that appears to be atrial fibrillation (AFib) is identified.

- Frost & Sullivan views this as a successive and timely geographic expansion into other major healthcare markets for Apple. Especially the Europe-wide clearance before the Brexit deadline will also make it easy to enter the UK market. Despite Apple Watch Series 4 being launched as a D2C device, the company claims to provide a professional on-boarding experience to educate the consumer on what atrial fibrillation is with a series of screens on user's iPhone explaining what the results mean. Frost & Sullivan views this as a critical feature considering the challenges with false alarm and lack of proper interpretation from wearables ECG devices leading to consumer panic and unnecessary doctor visits.

- **Target End-User:** Average Consumer, Insurance and Employee Health programs, Clinical Trials


How ECG reading is taken?

- The Digital Crown on the Watch contains an electrode and there's another one on the back of the Watch. When you touch the Crown, the electrode on the back touches your opposite wrist, completing a circuit.

- All you have to do is sit quietly, with your arm on the table, or in your lap, and after 30 seconds you have the result. The heart animation gives way to a red line which mimics your heart rhythm.

WEBLINK: https://apple.co/2Uj3odw

Study finds new program using Google Glass, AI helps children with autism interpret emotions – March 27, 2019

Applicable Product Categories: Wearables

Technologies	Augmented Reality, AI		**Therapeutic Areas**	Autism
Applications	Social training for autistic kids		**Geographic Focus**	Global
Segment Focus	Consumer Grade		**Topics (News type)**	Competitive Intelligence
Companies	Apple		**Others**	NA

ANALYST TAKE:

Synopsis: Published in JAMA Pediatrics, the investigation found that children using the new system showed significant improvements in socialization skills.

Industry Challenge: As per CDC, one in 59 children in the US have been identified with Autism Spectrum Disorder (ASD), and it four times more common in boys than girls. While behavioral analysis is recommended for children with ASD, it costs between $40,000-$60,000 per child each year.

Value Proposition: Named Superpower Glass, the new system was designed to "encourage facial engagement" and provide feedback on social situations. The program, which runs on Google Glass, helps kids classify the emotion of the person they are interacting with. Using machine learning, the tools is able to identify eight emotions, and then cue the child via a robotic audio clip and a visual emoticon. Families were also given a companion app, which lets the child's caregiver manage the system. As per the research findings, this is the cited as first randomized clinical trial to demonstrate efficacy of a wearable behavioral intervention for children with ASD.

Frost & Sullivan finds the results from this clinical validation as one more crucial research supporting the clinically meaningful and efficient application of wearables in healthcare space. Especially considering the limited drugs or curative treatment option for behavioral health conditions, clinically vetted wearables demonstrate a compelling growth opportunity in this space.

WEBLINK: https://bit.ly/2TISyJB

Mobile Phones/ mHealth

Scanwell Health moves beyond home UTI testing with nationwide kidney disease study partnership – March 28, 2019

Applicable Product Categories: Mobile Phones

Technologies	mHealth App		**Therapeutic Areas**	Chronic Renal Disorders
Applications	Home-based diagnostic tests		**Geographic Focus**	US/Global
Segment Focus	Clinical Grade		**Topics (News type)**	Innovative Business Model
Companies	Scanwell Health		**Others**	-

ANALYST TAKE:

- **Synopsis:** Scanwell Health, the maker of a smartphone-based platform for home urinary tract infection screening, announced last week that it will be playing a role in the Chronic Renal Insufficiency Cohort (CRIC) Study, an ongoing, multicenter investigation of chronic kidney disease and other comorbid chronic conditions sponsored by the National Institutes of Health.
- **Value Proposition:** As a result of the partnership, up 1,250 of the study's participants will be conducting their own monthly urine testing for kidney disease from the comfort of their own homes, thanks to a new version of the Scanwell diagnostic platform that's been designed to screen for the condition.
- Scanwell Health initially made its mark as the first FDA-cleared home urine testing app. Its UTI service asks consumers to urinate on the low-cost, mail-order test kit and take a photo of the results with the Scanwell app. With this, the company is able to connect users to an in-house physician at low cost and prescribe any necessary antibiotics within a single day.
- Frost & Sullivan believes, as part of this partnership in the CRIC study, Scanwell may be looking to expand its business beyond the consumer telehealth market and into the broader role of a "diagnostics as a service" company. Frost & Sullivan research projects DTC diagnostic test market to hit 1.2 billion by 2019, with a growth rate of 22.2%. Scanwell is also expected face competition from a number of players that have secured FDA clearances. healthy.io, TestCard, Mira and inui Health; and more importantly from leading diagnostic lab vendors such as LabCorp and Quest who have been expanding their DTC testing services.
- **Target End-User:** Average Consumer, Telehealth and Home Care providers

WEBLINK: https://bit.ly/2CUjCjB

Mental health apps plentiful, but few provide clinical research – March 25, 2019 (1/2)

Applicable Product Categories: Mobile Phones

Technologies	mHealth App;		**Therapeutic Areas**	NA (Care delivery workflow optimization)
Applications	Virtual Scribe		**Geographic Focus**	Global
Segment Focus	Consumer Grade		**Topics (News type)**	Innovative Application/ Use case
Companies	Sopris Health		**Others**	-

ANALYST TAKE:

- **Synopsis:** Researchers found that 64 percent of mental health apps claimed efficacy, although only 14 percent included any evidence.

- **Industry Challenge:** Estimates by the World Economic Forum, World Health Organization and the World Bank, the global cost of mental health illnesses in 2010 was about $2.5 trillion, which is expected to rise to $6 trillion, an annual loss to US businesses alone is expected to be as high as $440 billion. While the awareness around mental health issues is increasing, the shortage of professional workforce is a challenge – only 1% of the total global healthcare workforce is qualified or has trained for behavioral health issues. The surge in mental health apps in recent years aims to address this challenge – however, there are more than 3,500 mental health apps available on the app stores. Little evidence or a comparative assessment exists to prove the efficacy of these apps, leaving it up to consumers to try these apps for themselves.

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Value Proposition:

- "Although there is an increasing interest in accreditation processes, app libraries and frameworks to support clinicians in recommending mental health apps, personal searches on commercial app stores operated by the major smartphone platform providers remain a common method for discovering mental health apps," researchers wrote.
- But not all apps have gone through the same validation process. In fact, the same researchers conducted other studies with similar findings. "A preliminary investigation by the authors previously reported that, for apps clinically relevant for depression, 38 percent of app store descriptions included wording related to claims of effectiveness, whereas only 2.6 percent provided evidence to substantiate such claims," researchers wrote.
- Many used scientific language (44 percent) and supporting statements (64 percent) to make their claims. However, only 14 percent described a design or development involving lived experience, and none referenced certification or accreditation processes.
- Only two out of the 73 apps studied provided evidence from a study using the app. Additionally, the specific technique used to make claims was described in 33 percent of the apps.

- Frost & Sullivan notes that the healthcare industry needs clinical validation for acceptance from providers. But given that there are few mental health professionals, and many consumers prefer to search for digital health tools on their own, without consulting any professionals, many apps can possibly get away with little validation. This abundance of apps however, lowers adoption of the technology, and also discourages people genuinely needing help from trying the truly effective apps. Stronger accreditation processes and frameworks, where apps are vetted by the app platform provider (Apple or Google), or another entity will be a useful approach. Accreditors could benefit by building unique revenue models such as by collecting assessment fees, or royalties on app downloads, generating ad revenues on accredited apps, or by pushing their own products through the ecosystem of accredited apps.

- **Target End-User:** NA

WEBLINK: https://bit.ly/2TDxvIt

FDA regulations could create digital health opportunities for pharma – March 28, 2019

Applicable Product Categories: Smart Home Devices

Technologies mHealth, Wearables, and more

Applications Pharma applications

Segment Focus Clinical Grade

Companies -

Therapeutic Areas Digital Therapeutics

Geographic Focus US

Topics (News type) Regulatory News

Others US FDA, Novartis, Otsuka Pharma, Proteus Digital Health, Pear Therapeutics

ANALYST TAKE:

• "Changes made by the FDA have made it easier for digital health products to be cleared and approved, offering life sciences companies — and pharmaceutical companies in particular — the opportunity to accelerate approvals and improve provider and patient satisfaction," authors of the report wrote. "Companies willing to invest in strengthening or building digital competencies may win market share, while those without sufficient investments may find themselves at a disadvantage."

• Frost & Sullivan agrees with this view, but notes that the opportunities are also available for those entities who are willing to work with pharma companies for developing digital health tools. An example is mentioned in the article of Pear Therapeutics which teamed up with Novartis to develop the first prescription digital therapeutic approved by the FDA. The opportunity obviously does not lie only for startups, but also larger companies willing to work with healthcare incumbents to develop such tools.

WEBLINK: https://bit.ly/2HLb7eG

Smart Home Devices & Appliances

Could prescription vegetables be the future of healthcare? – March 23, 2019

Applicable Product Categories: Smart Home Devices

Technologies — AI

Therapeutic Areas — Disease prevention, management

Applications — Nutrition monitoring

Geographic Focus — US

Segment Focus — Clinical / Consumer Grade

Topics (News type) — Care Delivery Innovation

Companies — -

Others — CMS

ANALYST TAKE:

- "The authors of a new study conclude that healthful food prescriptions in Medicare and Medicaid would be more cost-effective after 5 years than preventive drug treatments.'
- Medicare and Medicaid are the two largest healthcare programs in the U.S., together covering one in three Americans and accounting for 1 in every 4 dollars in the entire federal budget.
- The positive effect on diabetes is due to the role that whole grains, nuts, and seeds play in diabetes prevention.

- Frost & Sullivan notes that nutrition or diet monitoring is an important part of health management, and as such views it as an important factor to monitor in the smart home. To effect such an exercise of ensuring people eat healthy would need diet monitoring and nudges – something that a smartphone maker can implement in the form of an app, as part of the health ecosystem of apps.

WEBLINK: https://bit.ly/2TtdsfF

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Other Interesting Articles

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

News Title	Link	Remarks
A major home appliance maker says hacking concerns are overblown	https://bit.ly/2OoAjrK	While in the current situation, home appliance makers' views on cybersecurity may be valid, the situation will be grave once all smart devices in the home are inter connected, at which point, only one weak link is necesssary to break in to the system. Target's 2014 hack is a great example – HVAC systems was the entry point for hackers. Smart home appliance makers wouldn't want the bad publicity associated then.
Comcast debuts $5-per-month 'Xfinity Flex' streaming platform and 4K HDR set-top box	https://bit.ly/2U1QHV2	Comcast's $5 servcie allows managing all smart home devices, with internet connectivity, streaming video service and control via their voice remote. This is a great value add service proposition, but greatly hinges on the compatibility issues for various connected devices to work with Comcast services; and some may prefer the touchscreen as an interface.
OK Google, stop terrifying my toddler: When smart homes make life miserable	https://bit.ly/2FIb8xs	We are still learning on how user interfaces should be designed – an approach where various scenarios on usage are tested in advance is a must.