The Increase of Wearables in Health: A Market Study

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This study aims to identify and characterize the most relevant medical devices to collaborate with in developing new technological resources for the healthcare market. A market study was carried out using the devices on the ANVISA platform. The chosen ones were divided into 5 scores, with 5 being the closest to the objective of the study, in order to compare their functionalities and connectivity. The number of features reveals that group 5 has had an average of 8.75 features per device, confirming the group with the most significant impact. However, further studies must list and analyze other health devices to categorize them, contributing to the production and advancement of this sector.
Keywords: Devices. Wearables. Sensory.

Introduction

Market Definitions and Context

Nowadays, there is a significant increase about health and well-being in all age groups. The National Health Survey (PNS), produced by IBGE, points out that in 2019 the average number of Brazilians who practiced the recommended level of physical activity during leisure time was 30.1%, while in 2013, this average was 22.7%, indicating a percentage increase in these indicators [1]. Regulated diet, physical exercise, and sleep quality are increasingly frequent guidelines. Concurrently, there is a growth of technologies that contributes to new emerging habits, such as Wearable Devices (Wearables) with health-related functions. Cooperation between technology and health has had existed for centuries, making it essential for their mutual evolution. Technological resources are essential in health support as they apply knowledge and skills to solve the population's health problems and improve the quality of life by creating devices, medicines, vaccines, and organizational and support systems [2].

Wearables allow continuous monitoring of the individual non-invasive and real-time by biochemical markers in body fluids, such as sweat, saliva, tears, and interstitial fluids [3]. Due to this, they help transform healthy activities into daily habits, allowing the individual to understand their evolution, set and achieve personal goals and prevent health complications, all with greater comfort and convenience, directly from their wearable. Another area with great potential for use is among senior citizens, especially considering Brazil's exponential increase in population aging. This population can benefit from continuous and remote monitoring of wearables, given the increasingly independent habits of the style of life among individuals in this age group [4].

Study Purpose

Due to the growth in demand for these products, the increase in investments in this technology area is also evident, resulting in the evolution and need for global adaptation to this new reality. In the second quarter of 2021 alone, this market saw a 32.3% increase in global shipments, with volumes reaching 114,2 million in this period [5]. Multinational technology companies such as Apple,

Samsung, Amazon, Google, and Microsoft have entered significant investments in the health market, expanding access to such devices and favoring a new stage in health care with interconnected systems and information [6].

The present work aims to identify and characterize the most relevant medical devices (software, hardware, or both) for use in a hospital, home, or outpatient environment, including their current and non-current resources available in the ANVISA database (National Health Surveillance Agency), in order to collaborate with the development of new technological resources for the health market, meeting the premises set forth by the regulations of this regulatory agency and by the demand and relevance in the current market.

Materials and Methods

A cross-sectional observational analytical study was carried out to establish the medical devices available in Brazil with applications in wearables for use in hospital, outpatient, and preventive medicine settings.

The search for devices was conducted on the ANVISA platform from June to October 2021, limited to devices registered in the health sector. As a result, 94,146 devices were found of the most varied types. Of these, after the inclusion and exclusion criteria were established, 393 remained.

The inclusion criteria were:
1. Medical devices;
2. Software (whether or not linked to hardware);
3. Registered on the ANVISA platform, whether in force in their registration or not.

The exclusion criteria were:
1. Hardware-only devices (without proprietary software);
2. Imaging devices (PACS - Picture Archiving and Communication System).

Thirty-two devices were selected according to the relevance criteria. We did the screenings in 4 stages:

1. Screening by inclusion and exclusion criteria in the database;
2. Evaluation of the provisions by 3 independent reviewers, with disagreements resolved by consensus after discussion;
3. Classification of devices' relevances was performed with a score of 1 to 5, with 5 being the closest to the study's objective, by 3 independent reviewers, with the final relevance score calculated from the simple average of the scores. Each reviewer received all information about the device, its features, and its applications.
4. Compilation of each device's available functions and connectivity features into a table to compare them (Table 1).

Results and Discussion

Based on the review of the selected devices, the great potential and technology embedded in these devices presented in the ANVISA's table are evident. There are, therefore, trends, as among the most frequent features, there are primarily vital cardiac signs, with Heart Rate (HR) present in 12 devices of the total analyzed, followed by Blood Pressure (BP) in 11 devices and Electrocardiogram (ECG) in 8 devices. The fourth most frequent functionality is Oxygen Saturation (SatO$_2$), present in 7 devices, followed by two functions tied for fifth place: Glycemia and Irregular Heart Rhythm Detection (ICR) in 6 devices. Appearing on 5 devices each, Fall Prevention and Body Temperature appear, followed by CPAP/Apnea, the functionality available on 3 devices.

Regarding the total amount of functionalities (33 described in the table attached to the article), we noted that 16 are present among the four devices in the group rated 5, an average of 8.75 functionalities per device; therefore, the group with more significant impact. Likewise, the 4 devices in the 4th-grade group include 9 of the 33 features described, with an average of 4.25 features per device. On the other hand, in the grade 3 group, 9 of the 33 features described for having 7 selected devices had

Table 1. Criteria used in each relevant track.

Score	Classification Criteria
1	Challenges to convert to wearable: No long-term monitoring; In-hospital only; Difficult to connect to other devices; Monitor any vital signs.
2	Possible conversion to wearable; In-hospital only; No connection to other devices; Analysis is not real-time; Possible integration with Health Service.
3	Possible conversion to wearable: In and Out of Hospital; Connection to other devices/data storage; Non-portable; Real-time monitoring.
4	It has hardware: In and Out of the Hospital; Connection to other devices/ data storage; Portable; Real-time monitoring
5	Wearable: In and Out of Hospital; Real-time monitoring; Connectivity to other devices/data storage.

**Figure 1.** More frequent features for the number of devices.
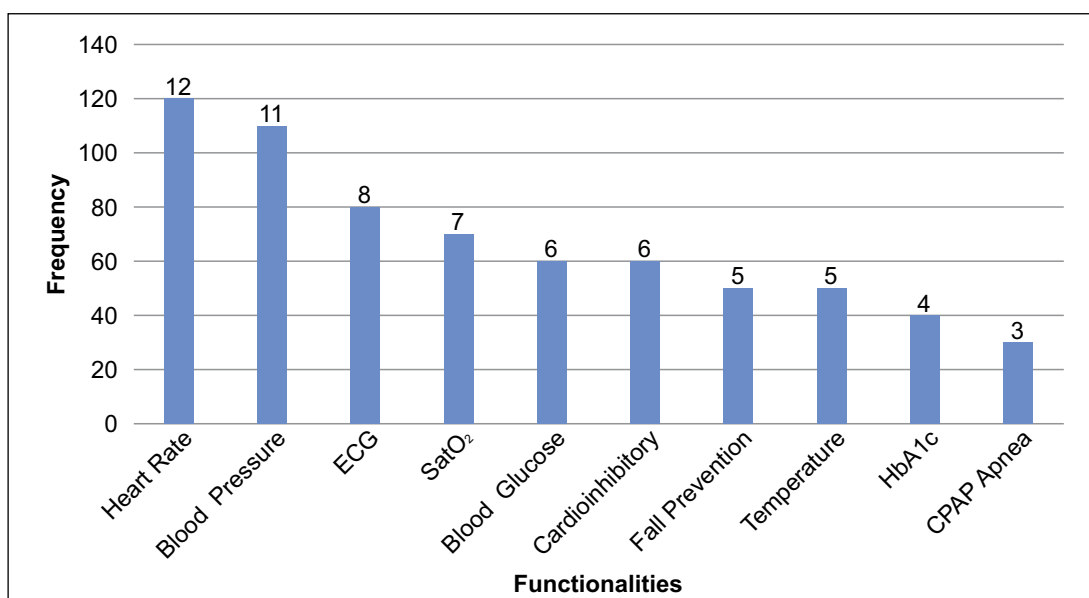
an average of 1.42 features per device. The grade 2 group, composed of 10 devices, included 13 of the 33 features, with an average of features per device 3.2. Also, the grade 1 group, with 7 devices, presented 11 of the 33 functions analyzed, reaching an average of 2.57 functionalities per device.

On the other hand, one can also point out the presence of particular features which appeared in only one device, such as Suggested Iron Dosage, Stroke Risk, Eye Pressure, Noise Monitoring, Neural Network Mapping, Fecal Calprotectin, and the Infusion Pump.

Bearing in mind the infinity of variables in the selected devices, both in terms of their functionalities, connectivity options, and the design of the products (size, shape, weight, and materials used), it became clear the need to classify these of relevance, to facilitate a macro analysis of similar devices. Because of this, we developed the relevance criteria in 5 grades in search of a product that, in our conception, would be the closest to ideal.

It would be a portable device (preferably wearable), which can monitor vital signs in real-

Figure 2. The total number of features presented in each score.
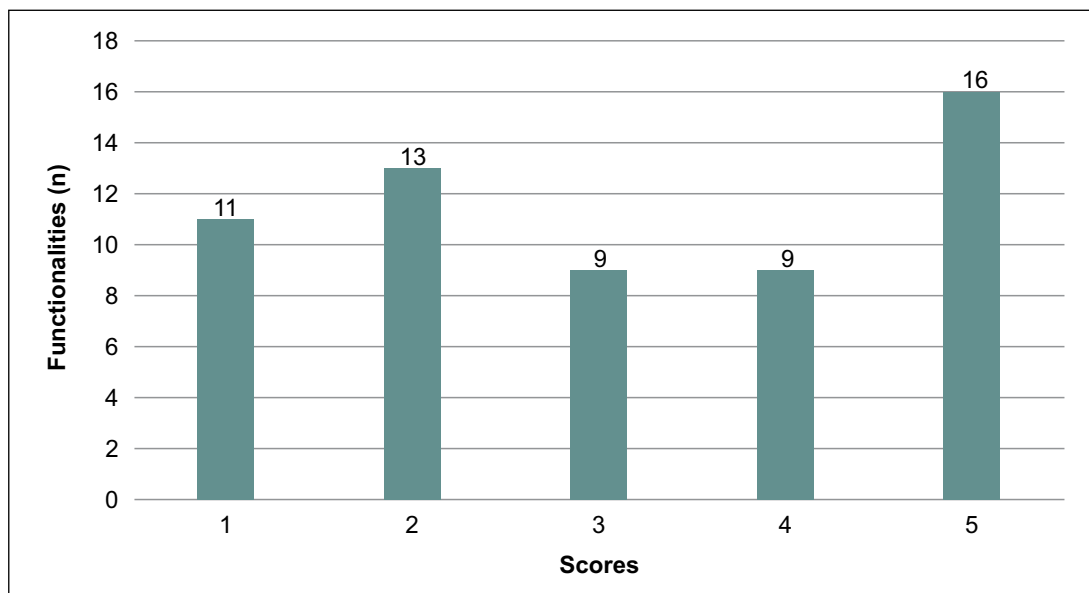
time, allows connectivity with other devices (and thus information traffic), and has data storage capacity so that the parameters records are not lost and can be used for in-depth analysis by algorithms and professionals, in addition to maintaining patient history. In addition, use resistant materials while having a competitive market price and being accessible to different social classes. It is also interesting that it can be used in different environments, both hospital and home, and its features adapt to the needs of each user.

Based on the average functionality data per device, it is evident that despite being portable (since one of the criteria for inclusion in the group is to be wearable), the devices in the grade 5 group have more technology embedded in each of their devices, while being small, light and versatile, making them the devices that most resemble the one proposed by the project. Based on this, the devices included in this classification category are the closest to ideal. They are wearable, capable of home and hospital use, have real-time monitoring, storage, and connectivity with applications and other devices, and are already available and validated by Organ's competent bodies in the Brazilian market.

Of the four devices selected, the devices in the grade 5 group, Galaxy Watch and Apple Watch fit as watch-shaped wearable devices, which have features such as heart rate monitoring, pulse oximetry, irregular rhythm notification, sleep monitoring, and detection of drop, among other functions (Table 2). On the other hand, the Libre Link device, through daily measurements, estimates the user's glycated hemoglobin using a minimally invasive sensor, which, when passing the reader that comes with the kit or the user's smartphone, allows the reading of glucose, its trend (increasing, decreasing or stable), the development of graphs and the estimated calculation of glycated hemoglobin, through the daily values - factors that made it be selected for group 5. Finally, the Wipple device has a portfolio of medical devices connected devices that can be used by synchronizing them with the Wippe Track application, thus taking advantage of features such as monitoring physical activity (calories spent, kilometers traveled, number of steps) through a wearable watch type, digital scale, Portable ECG and digital blood pressure monitor, which detects HR, BP, and RCI.

When it comes to device connectivity, the Apple Watch and Galaxy Watch are once again on

Table 2. Features available on score 5 devices.

Functionalities	Devices Score 5			
	Apple Watch	Galaxy Watch	LibreLink	Wippe
Altimeter	x	x		
Digital scale	x			x
Compass	x	x		
Cellular connection	x	x	x	x
Falls Detection/Prevention	x	x		
ECG	x	x		x
Heart rate	x	x		x
Glicemy			x	
Noise monitoring	x			
Sleep monitoring	x	x		
PA monitoring	x	x		
Water resistance	x	x		
Dust resistance	x	x	x	
Irregular heart rate	x	x		
SatO$_2$	x	x		x
SOS Emergency	x	x		

par, offering the user a range of options, including LTE, Bluetooth 5.0 (which has the advantage of spending less battery), Wi-Fi, NFC (Near Field Communication, short-range wireless network), A-GPS (Assisted Global Positioning System - which uses the cellular network to improve GPS performance) and/or GLONASS (Global Navigation Satellite System in Russian) and UMTS (3rd generation operators, popularly known as 3G) (Table 3).On the other hand, the Libre has only the NFC sensor, which transmits glucose data to the reader of Abbott's authorship or a smartphone with this technology (iOS or Android devices), making the device even more practical. Wippe, in turn, has only Bluetooth 5.0 available to connect its four devices to the user's smartphone.

With the progress of this study, the number of functionalities in the most different devices already available in the national market for different applications becomes evident. In this sense, we notice a great potential in Wearables to contribute to medical care in the world, automating processes, preventing comorbidities and accidents, and collecting data beyond the hospital environment, which with the use of these devices, can be much faster and more accurate, avoiding thus the loss of data from medical records and fraud. Furthermore, it allows us to verify that we already have the technology, the regulation by competent institutions, and the economic market that demands this type of device in our national territory.

Conclusion

Briefly, a current study of health devices present in Brazil, according to the ANVISA platform, was addressed in this work, analyzing their functionalities, connectivity, and importance in the current scenario. The relevance of this theme was noted because of the increase in the world

Table 3. Connectivity options available on score 5 devices.

Connectivity	Devices Score 5			
	Apple Watch	**Galaxy Watch**	**LibreLink**	**Wippe**
LTE	x	x		
Bluetooth 5.0	x	x		x
Wi-Fi	x	x		
NFC	x	x	x	
A-GPS / GLONASS / Beidou 7	x	x		
UMTS	x	x		

market for these devices, their production, and their relevance in the daily life of the population. It is concluded that the most used/relevant features were heart rate, blood pressure, and ECG, indicating concern with cardiovascular diseases that are the leading cause of death in the world [7].

The initially proposed objective of identifying and characterizing the most relevant medical devices (software, hardware, or both) was achieved, as detailed in the attached table. Finally, it is suggested to deepen market studies that list and analyze the other health devices in the world market to categorize them, contributing to the production and advancement of this sector and stimulating, in fact, their application to the final customer.

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