Design and development of an IoT device provided with a voice interface to improve treatment adherence in polymedicated patients

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***Abstract*— The population pyramid is inverting in the Western world, and this demographic transition brings new challenges. The search for healthy aging has made the use of new technologies for assistance, not only in specialized centers but also in the home itself. In recent years, many advances have been made in medical devices at home, with particular emphasis on devices to help take medication. The poor (or not) following of the instructions given by the medical personnel to the patients for taking medication causes thousands of avoidable deaths every year. In this work, a new approach to smart pillbox is proposed, combining the power of voice assistants with telecare devices. An smart pillbox with integrated Alexa was developed, and the foundations are laid for the use of voice assistants in healthcare.**

***Keywords*— smart pillbox, telecare, medication, adherence, Alexa, IoT, IoMT, e-Health**

I. Introduction

If 100 years ago life expectancy was drastically lower, due to the lack of effective drugs for diseases that generally should not be fatal, today countries such as Japan or Spain have the highest life expectancies globally.

This demographic change requires changing the paradigm of aging. It is not sustainable to continue with the consideration of being a stage of inevitable physical and mental deterioration. It is necessary to evolve towards preventive and predictive medicine to detect problems early and avoid diseases [1]. Healthy aging aims to extend people's period of independent life, improving their quality of life and keeping them within their home and environment.

However, associated with this preventive medicine, new risks have appeared, particularly by patients with chronic diseases, who cannot follow the treatments established by their doctors, which causes unnecessary admissions and, in the most severe cases, can lead to death of patients.

In primary care, up to 40% of polypathological patients have three or more chronic diseases. Of these, 94% are polymedicated, so it is essential to follow an adequate therapeutic adherence strategy to ensure control of the disease [2]. According to the Ministry of Spain, from the point of view of health resources, patients with chronic pathologies are the 80% of consultations in primary care centers and represent 60% of hospital stays, especially in unscheduled admissions [3].

According to the WHO (World Health Organization), 50% of patients suffering from chronic diseases do not follow the treatment established by their doctor. Poor adherence to long-term therapies affects the effectiveness of treatment, quality of life, and costs. Among the different factors that influence adherence is age: older people represent 6,4% of the world's population, increasing every month. People over 60 years old consume approximately 50% of all prescription medicines in developed countries. Adherence to treatments is essential to the well-being of elderly patients [4].

The global problem of aging and the inversion of population pyramids translates into an increase in polymedicated older people [5]. A polymedicated person is considered to be a person who consumes more than five medications a day for more than six months. One of the most significant challenges arising from this problem is the lack of adherence caused by non-compliance with the established treatment.

The WHO estimates that non-adherence contributes to around 200,000 premature deaths each year in Europe, with a cost to the health system of 125,000 million euros [6]. In Spain, the lack of adherence generates an expense of around 11,250 million euros annually and 18,400 deaths related to this cause [7].

These data highlight the magnitude of the health problem that this lack of adherence entails. So much so that even the European Council launched within the Horizon 2020 program a "Call for Proposals" [8] for the development of policy recommendations that improve patient adherence and guarantee the safe, effective, and profitable use of medicines in Europe.

This article describes a design of an e-Health device. Not only built as a R&D (Research and Development) example but with the aim of being commercialized by a local company, BYTEK Smart Solutions [9]. It is creating a non-invasive IoT ecosystem that improves personalized health and safety at home, through various sensors that collect data on the medical habits of users. The first device in the IoT ecosystem is Pileus [10], a smart pillbox, an e-health device with voice control through Alexa, Amazon's virtual assistant. Pileus also acts as a wireless hub to connect other devices in the home telecare ecosystem. The device houses 28 packs that allow preparing the necessary medication for a week, and it indicates with a light which of them we must open at the time of each dose. Once the user presses the button indicating that the pill has been taken correctly, the pillbox will transfer that information to the digital platform. It not only reflects the patient's daily activity to monitor the treatment but also facilitates the control of the caregivers -who can receive notifications in real-time when the pillbox warnings are not heeded [11].

This paper describes the development of a prototype of a smart pillbox with voice control in order to improve the adherence of aging polymedicated patients to their medical treatment: Pileus. After this introduction, the state of the art is presented, then requirements of the prototype are analyzed and the proposed design is described. Then, achieved implementation and results of the prototype are shown, ending with some conclusions.

II. State of the Art

As healthcare is transitioning from traditional disease-focused office care to continuous, personalized care anytime, anywhere, digital health and "connected care" are gaining impulse [12]. This is called IoMT (Internet of Medical Things) [13], whose objective is to provide health, clinical and medical education services from one site to another, in order to offer faster and more efficient diagnosis and clinical care.

The IoMT is a connected infrastructure of health systems and services designed to identify problems before they become critical and enable early intervention by caregivers.

One area in which has been explored the IoMT is medication management. Most caregivers who administer medications to the elderly in nursing homes agree that the time spent preparing and administering medications is too high [14]. In addition, the human error must also be taken into account when preparing the medication, especially if it has to be prepared four times a day for more than 20 patients.

Studies have analyzed the prevalence and potential harm of medication prescription, monitoring, dispensing, and administration errors [15] and have concluded that nearly 70% of residents have had one or more errors. [16].

For this reason, solutions have emerged in the scientific literature to facilitate the work of elderly caregivers, particularly in nursing homes and hospitals [17]. In follow-up studies, results have shown that most carers thought that these solutions were useful in reducing medication errors and in assistance with medication.

Another research target is to make pillboxes that facilitate the autonomous taking of medications by each user at home. Many of these smart pillboxes are based on using a stationary pillbox in the patient's home that only allows the dispensing of the medication that has to be taken at any given time [18]. The biggest problem faced by this type of pillbox is the mechanics involved in dispensing and the errors that it can generate. Other pillboxes follow another approach [19], utilizing a mobile notification: the patient is notified that it is time to take the medication, also explaining which one they have to take. Other prototypes also have a notification system that alerts caregivers when the patient has not taken a medication [20]. Furthermore, other prototypes [21] have wearables such as bracelets to remember to take medication. Those solutions, in general, have a common element, which is the use of a mobile app. However, most of them are not adapted to the elderly audience and do not take into account the vision and maneuverability problems that these people suffer when using a mobile phone [22]. There have been studies [23] showing that poor UX/UI (User Experience/User Interface) leads to much less user retention and users who have difficulty to navigate an app are less likely to continue using it, especially older ones.

In this research area, it is being produced a jump from research to the company where it can be found different examples, national and international, that have focused their efforts on the smart pillbox sector: Ima (Berdac Smart Services) [24]: Spanish startup based in Barcelona and founded in 2019, whose main product is IMA (Intelligent Medication Assistant). MedMinder [25]: Company founded in Massachusetts, United States, in 2007, to manufacture products that simplify medication management and improve medication adherence. MedFolio: [26] Company born in 2008 in San Francisco, United States, to facilitate the management of medical services between patients and pharmacists/doctors, with the creation in 2011 of MedFolio Electronic Pillbox. Pillo Health [27]: Startup born in Boston, United States, in 2014, to solve the problems present in the US regarding the lack of adherence in taking medication. Its main product is Pria.

III. Requirements

In order for the design of the device Pileus to meet the desired functionalities and, at the same time, pass all the necessary certifications, the following requirements are collected.

A. Physical

It starts with designing a complete 3D model of the device case. Fig. 1 shows an exploded view of the elements that make it up. The device follows the usual 4-taking/day refillable pillbox format usual on the market.

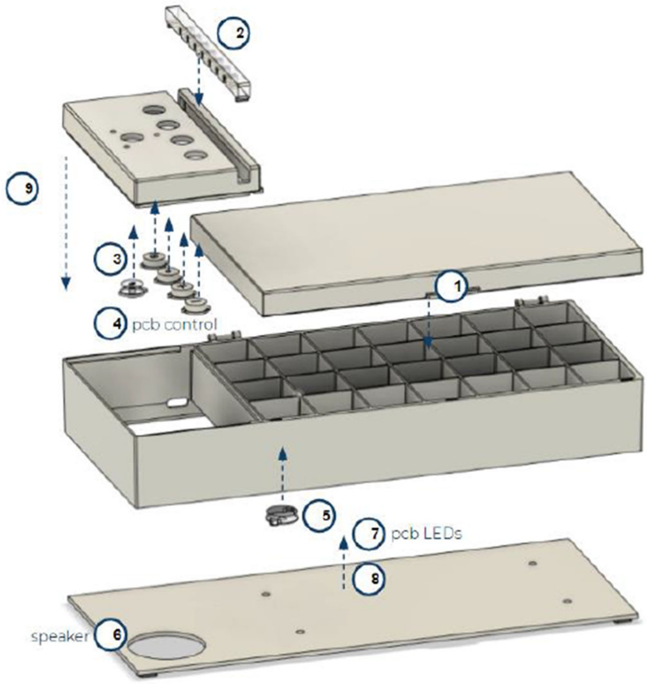


Fig. 1. Exploded view of Pileus without electronics.

Considering the design of the 3D model case and the space available to accommodate the electronics, there are two electronic boards: the control board and the LED (Light-Emitting Diode) one, and their sizes are given by case dimensions.

- Control card. It is located at the top of the device. This must contain, due to its location, at least:
  - Microphones.
  - Pushbuttons.
  - RGB LED bar.
- LEDs card. The locker card in the taking matrix. Its main mission is to illuminate the square corresponding to each shot. This card must contain at least:
  - 28 high brightness green LEDs.
  - USB type C connector for device power and firmware upload.
  - Speaker connector.

B. Electronic

The device must comply with a series of mandatory characteristics.

- Powered by an USB type C connector with the implication of power that it may entail.
- Being Alexa Built-in [28] with the commitments that this entails: sufficient processing capacity; RGB LEDs that indicate the states of Alexa (an essential requirement to pass the Amazon certification [29]); speaker; four control buttons with different functionalities; wireless network interface to access the Internet.
- Backlit button to monitor adherence.
- Bluetooth to connect with the mobile application for device configuration.
- At least 28 LEDs for lighting each locker.
- Have the best possible cost/performance ratio without compromising functionality.
- It must pass the relevant tests for this type of product related to electromagnetic compatibility to obtain the European CE conformity marking, like any electronic device to go on the market.
- The use of through-hole components should be avoided to facilitate the manufacturability of the card.
- The use of components in the commercial temperature range is allowed. It can be compared to any household appliance commonly used in the home.

- Due to the nature of the use cases of the device, it is intended to have the lowest possible failure rate. To this end, the objective is established to have a value of MTBF (Mean Time Between Failures) of at least 100,000h (more than ten years) in normal environmental conditions (25ºC).

C. Security

Due to the large number of devices transmitting sensitive medical data wirelessly to the cloud, IoMT is highly exposed to security and privacy breaches. Therefore, ensuring the security and privacy of IoMT becomes an urgent issue, in which much focus is placed on the research field [30]. Another critical point in the security of IoMT devices is OTA (Over the air) updates. When making these updates, precautions must be taken to prevent attackers from exploiting the vulnerabilities. Semiconductor manufacturers have also focused efforts on developing security chips that allow cybersecurity functionalities to be implemented at a lower level. For example, NXP Semiconductors has developed the A71CH chip [31], its first out-of-the-box secure element. This IC offers end-to-end security, from the IC itself (on the device) to the cloud. It is a platform capable of securely storing and provisioning credentials, connecting IoT devices to cloud services, and performing node authentication.

IV. Design

The electronic design of the Pilelus is divided in different parts:

A. Microcontroler Unit

In this design, the most crucial part, and on which the rest of the decisions are based, is the selection of the MCU (microcontroller Unit) since the rest of the peripherals will be connected to it.

NXP's i.MX RT106A hybrid microcontroller has been selected. It is an MCU from a new family of NXP MCUs for edge computing [32]. This microcontroller implements an ARM Cortex M7 capable of operating up to 600MHz to offer real-time response through an operating system (such as FreeRTOS or Zephyr).

NXP has specifically designed this MCU to implement Alexa at the best possible performance/cost ratio instead of more expensive to implement MPU-based designs.

This implies that some functionalities are already pre-certified. The solution has been qualified and pre-certified by Amazon to work with AVS (Amazon Voice Service), and FFS (Free Frustration Setup) built on top of ACS (Amazon Common Software). FreeRTOS real-time operating system for easy deployment with AVS and AWS (Amazon Web Services) IoT to include future new features and applications that Amazon implements in the cloud.

B. Software

The amount of software and examples already made with the integration of Alexa Another is another positive point to select the i.MX RT1060 processor from NXP. In addition, the development kit offers pre-certified software [35] by Amazon for Alexa integration, including all necessary libraries, cloud communications, local processing, and security layers. Starting with pre-certified software significantly shortens the certification process that Alexa built-in devices must go through to go on sale.

C. Amazon FreeRTOS

The device's MCU runs a real-time operating system, particularly Amazon FreeRTOS [36], to facilitate integration with Amazon Cloud Services (AWS). Amazon FreeRTOS is a real-time operating system that extends the FreeRTOS Kernel with security libraries, connectivity, and update capabilities.

The Pileus device uses this operating system and builds on it all the necessary elements to integrate Alexa. Fig. 2 shows a high-level schematic of the firmware running on the device.

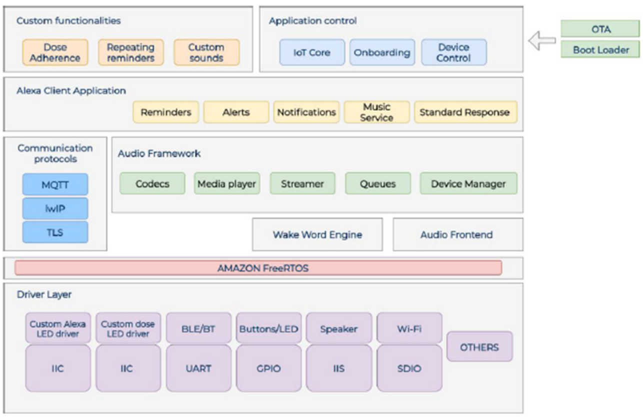


Fig. 2. Stack firmware of Pileus.

Other interesting Amazon FreeRTOS extras are:

Support for securely connecting devices to a local network via WiFi or Ethernet.

- Data encryption and key management (PKS #11).

- Transport Layer Security (TLS v1.2) support to connect securely to the cloud.
- Support for MQTT (Message Queueing Telemetry Transport) and OTA (Over The Air) updates.

D. Power

The power of the device is obtained from a commercial source with a 10W (5V@2A) USB Type-C output connector. Then DC/DC converters are used to obtain other needed voltages: 1.8V and 3.3V.

E. Audio: Microphones and amplification

The audio part is composed of an amplifier, an EMC (Electromagnetic Compatibility) filter, and the connector to the speaker. The amplifier chosen is the TFA9894 form NXP, a class D amplifier with integrated codec and DSP, connecting to the microcontroller through its SAI (Synchronous Audio Interface) interfaces.

The audio pickup part is composed of three digital microphones instead of two to support 360º far-field recording. The microphones connect to the microcontroller through another SAI interface.

A fundamental element in the design of a device based on a voice assistant are the microphones. In recent years, the use of MEMS (Microelectromechanical systems) type microphones in consumer electronics. Their high performance and small size make them ideal for this type of design where miniaturization is a critical factor. However, in the implementation of the design, not only the parameters of the microphone itself must be taken into account, but also the entire acoustic path of the device, from the input of the sound mechanics to the microphone port itself [33]. This type of cavity (Fig. 3) is known as a Helmholtz resonator.

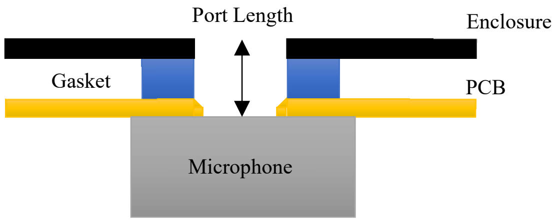


Fig. 3. Profile view of the PCB with the microphone and mechanics.

The central resonance frequency is given by the following equation (1):

$$f = \frac{cD}{4\sqrt{\pi V\left(L+\frac{D}{2}\sqrt{\pi}\right)}} \qquad (1)$$

Where c is the speed of sound, D is the hole port diameter, V is the volume of the hole port and L is the length of the port. It is desirable that said resonance frequency be outside the range of the signal to be captured [34], which in this case is the human voice that ranges approximately between 125 Hz and 8 kHz. I this case, for selected dimensions: f = 10.45 kHz.

F. Lighting - LEDs

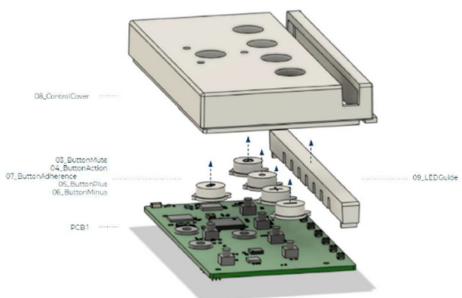
As there is a need to independently control the LEDs of the RGB (Red Green Blue) status bar, the box LEDs, and the two buttons' LEDs, it is decided to add two specific external controllers for LEDs with a control interface via I2C (Inter-Integrated Circuit).

On the one hand, the LP5024, which has 24 outputs, controls the 8 RGB LEDs. On the other hand, the LP5030 has 30, 28 of which will be used for the green LEDs of the locker.

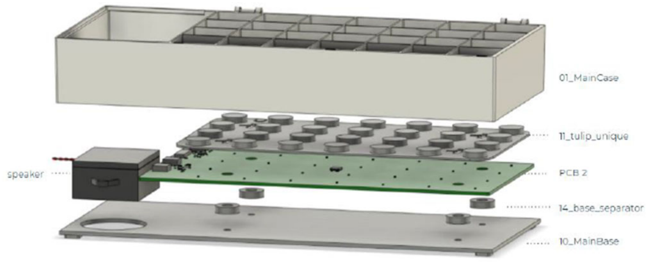
Two GPIOs, respectively, control the two remaining LEDs corresponding to the backlit button.

V. Results

Fig. 4 shows the fit of 3D renderings of the electronic cards with the mechanics and their positioning. Fig. 4a shows the control part, and Fig. 4b the LEDs part where medication is placed.



a) Control part.



b) LEDs part.

Fig. 4. Assembly detail.

Fig. 5 shows the control card and the LEDs card, once manufactured, ready to be assembled in the mechanics.

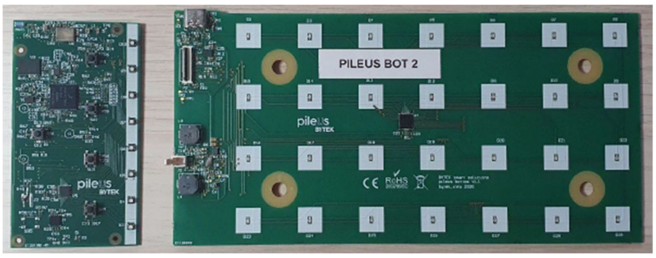


Fig. 5. Electronic card prototypes.

Fig. 6 presents the prototype finished with all the elements assembled. The case of the device prototype has been made using the SLS (Selective Laser Sintered) 3D printing technique.

Fig. 6. Pileus prototype.

Apart from physical assembling other technical parts of the prototype are analyzed. The firmware installed on the device and, in particular, the cybersecurity elements implemented in it are also probed.

- The connection of the IoT Core to the cloud. Fig. 7 shows how Pileus device has been connected to the could using an associated certificate.

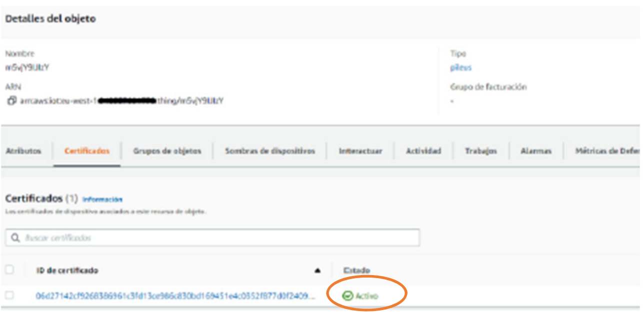


Fig. 7. Detail of the IoT Core connected to the cloud: Active ("Activo").

- A unique certificate is associated with each Pileus device. The way to identify the devices is using their "Serial Number." By associating certificates with device serial numbers it is ensured that the equipment connected to the IoT Core using those certificates are actually the Pileus devices that are authorized. Fig. 8 shows the certificate used in the case of this Pileus that is being tested.

Fig. 8. Detail of the certificate.

- OTA update of the device firmware has been performed to analyze the implemented security mechanisms. Fig. 9 shows a new work created for an OTA update in the IoT console. Fig. 10 shows that the update has been successfully completed.

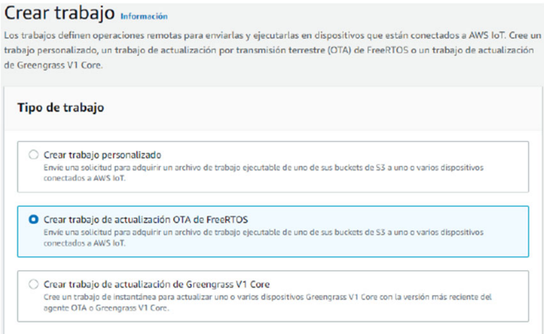


Fig. 9. Detail of IoT console.

Fig. 10. Detail of succes update: Completed (“Completado”).

Finally, regarding the value obtained from MTBF, the required value of 100000 hours is far exceeded. Taking into account selected devices and components the reliability of the Pileus is estimated obtaining a good value of MTFB = 482687 hours.

The basic operation of the device is as follows. The device's alarms are previously programmed through a mobile application. Then, it notifies the user by voice and sounds when the patient has to take the medication, lighting up the corresponding box where the pills are located. Finally, there is a semi-translucent button that will remain illuminated (blinking) until it is pressed to confirm that the shot has been taken correctly and to be able to monitor treatment adherence.

VI. Conclusions

The Pileus, a pillbox with an integrated Alexa voice assistant, has been designed, and a prototype has been done. Set goals have been achieved: design and make the electronic schematics, design and manufacture the PCBs of the device, and assemble the components that make up the prototype complying with the specifications and within the foreseen deadlines and costs.

Nevertheless, different steps are still needed to be able to bring it to market. In particular, a future line of work is the study and performance of the necessary tests to obtain Amazon certification and sell the product under the Alexa brand. On the other hand, it would be very interesting to carry out a focus group in an environment with the target audience of the device to analyze its usability and to be able to detect design problems.

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