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Design and Validation of an Optimal Mechanical Enclosure for Low-Cost Real-Time Gluten Detection Using NIR Sensor in a Portable Device

Unai Sainz Lugarezaresti*, Oscar Jossa-Bastidas, Uxue García Ugarte, Guillermo Yedra Doria, and Begonya Garcia-Zapirain

eVIDA Research Group, University of Deusto, 48007 Bilbao, Spain

ABSTRACT

Food allergy, specifically gluten intolerance, is a significant global health issue affecting approximately 7% of the population, with the only effective treatment being lifelong adherence to a gluten-free diet. Despite the need, no rapid, low-cost, non-invasive testing device is available for patients with this disease. This research, conducted within the TECAM project funded by the Basque Government and in collaboration with Leartiker and CEIT, aims to design and implement a technological solution for celiac individuals to query gluten contamination of food samples in real time using a low- cost device based on a near infrared (NIR) sensor (DLP NIRscan Nano), with a focus on the mechanical design and validation of the sensor's integration for optimal NIR spectroscopy. Evaluations of environmental impacts on sample acquisition highlighted the significance of various disturbances like sensor height, light exposure, device temperature, and sample preparation, with tests using the SparkFun AS7263 sensor showing the importance of minimizing sensor height and external turbulence. This necessitated a closed, opaque enclosure, designed with CAD tools and 3D printed, with its efficacy validated using the "Software Usability Scale" (SUS) and "USE Questionnaire". Twenty prototypes were created during this iterative process, and the final design successfully integrates the DLP NIR scan Nano sensor, aligning with the design 4 all philosophy and ensuring optimal sensor functionality. Conclusively, this study offers a low-cost, portable design for a NIR sensor integration to detect gluten, emphasizing the need to minimize environmental disturbances and incorporating user feedback to produce a practical tool for celiacs to non-invasively assess gluten contamination quickly.

***Corresponding author**

Unai Sainz Lugarezaresti, eVIDA Research Group, University of Deusto, 48007 Bilbao, Spain.

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Introduction

For celiac patients, it is of great importance to ensure that the foods they consume will not cause any symptoms [1]. Common symptoms may include vomiting, lip swelling, or rhinitis, among others, but more severe reactions can lead to anaphylactic shock, which can be fatal [2].

In Europe, it is estimated that approximately 150 million people suffer from chronic allergies, and it is projected that by the year 2025, 50% of Europeans will experience some form of allergy [3]. Among those affected by gluten are individuals with celiac disease and those who are gluten intolerant but not celiac. Although gluten intolerance or celiac disease is not considered an allergy, it is a multisystem disorder that also requires a gluten-free diet as the only solution.

However, maintaining this diet poses a challenge due to contamination that exists in products labeled as "gluten- free." This contamination can occur at various stages, from harvesting and transportation to food processing. Even in bakeries and food processing facilities, complete equipment decontamination is practically impossible. In fact, research has shown that some products labeled as gluten-free exceed safe limits, with gluten levels surpassing 20 mg/kg, the threshold for being considered gluten-free. Therefore, it is essential for gluten-intolerant individuals to have certainty that the products they consume comply with established limits and will not trigger adverse reactions. Ensuring food safety for these patients is a crucial goal in the field of biomedical engineering.

Currently, studies have demonstrated significant progress in gluten detection through rapid analysis tools [4]. Notably, research conducted by the eVIDA research team has demonstrated the capability of NIR technology and Artificial Intelligence to detect gluten contamination in flour samples with up to 92% accuracy [5]. However, none of the previous studies have considered the usability of the device by users affected by the phenomenon. Hence, this paper focuses on the design of a mechanical device suitable for all types of users, enabling the integration of positive results obtained by professionals with non-expert users.

The primary objective of this study is to design and validate a user-friendly mechanical device for gluten detection, with a focus on usability by individuals affected by gluten-related conditions. This device integrates NIR technology and Artificial Intelligence to enhance gluten detection accuracy. The study also aims to determine optimal operating conditions for NIR sensors and assess the usability of the device through practical testing.

Methodology

The methodology adopted in this research project encompassed several stages, meticulously designed to develop a robust, user-friendly, and efficient device for gluten detection. The various steps undertaken during the research are delineated below:

1. **Sensor Measurement Acquisition:** The initial phase involved capturing measurements from the sensors to understand their operational parameters and the potential influences on their performance.
2. **Prototyping with SolidWorks2020:** Subsequently, prototypes were developed using SolidWorks 2020 to ensure secure sensor grip, thereby preventing direct contact and potential contamination. The design focused on ergonomic handling and ease of use, facilitating seamless integration into the final device.
3. **3D Printing of Prototypes:** Once the preliminary designs were ready, they were materialized using 3D printing technology. This process enabled the creation of tangible prototypes that could be easily modified based on the experimental findings.

4. **Data Analysis:** All the data collected during the experiments were recorded in CSV files. Python, along with the Pandas library, was employed to analyze the data. This step facilitated the extraction of meaningful insights from the collected data, which played a pivotal role in the subsequent stages of the research.

5. **Experimental Trials:** Several experiments were conducted in this phase to:

- Determine the optimal sensor height for accurate readings.
- Identify potential external disturbances that might alter the measurements, thus formulating strategies to mitigate them.
- Assess the necessity of sample preparation to facilitate accurate readings.
- During these experiments, new prototypes were designed as needed to aid in data acquisition and refine the operational aspects of the device.

6. **Final Prototype Design:** Leveraging the insights gained from the analyses, a final prototype was developed, embodying the "design for all" philosophy to ensure usability for a wide range of users. This design incorporated all the findings from the previous stages, aiming to create a device that is both effective and user- friendly.

7. **Usability Testing:** In the final stage, usability testing was conducted using the "Software Usability Scale" (SUS) and the "USE Questionnaire: Usefulness, Satisfaction, and Ease of Use". These tests served to identify and rectify usability issues, based on feedback from volunteer users, further fine-tuning the device to meet the users' needs and preferences.

Throughout the research, iterations were made as necessary (mainly steps 1 to 5, as seen in Figure 1) to ensure the development of a device that not only meets the technical specifications but also addresses the usability considerations crucial for widespread adoption.

Experimentation and Results

The experiments consist of technical tests to analyze physical properties, functional testing, and verification of results. The experiments were conducted using the baseline design of prototype 1. The information gathered from these experiments was applied in the final design of prototype 2.

A. Prototype 1

Before conducting the experiments, prototype 1 was developed. This prototype is compatible with sensors from the

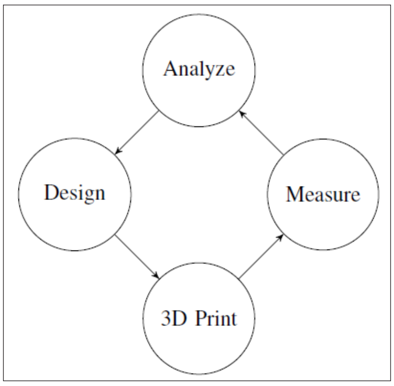

Figure 1: Diagram of the Iterative Cycle of the Research Methodology

Spark Fun family. The experiments described in the following sections were based on this prototype. The components manufactured for prototype 1 are as follows:

• **Sensor Sleeve:** As the AS7xxx sensor family had varying dimensions and complex geometries, it was decided to design the final device in two parts: a sensor sleeve and an enclosure. The purpose of the sleeve is to accommodate different and diverse sensors within the same main casing (enclosure). In other words, its function is to standardize the sensor size. These sleeves have sleeves that act as rails to fit into the enclosure (see Figure 2). The exterior dimensions of the sleeve are the same for all cases, with only the interior varying to accommodate the shape of each sensor. This design effectively acts as an adapter between the sensor and the casing. Thanks to these sleeves, the same enclosure can be used for different sensors, each with different shapes and sizes.

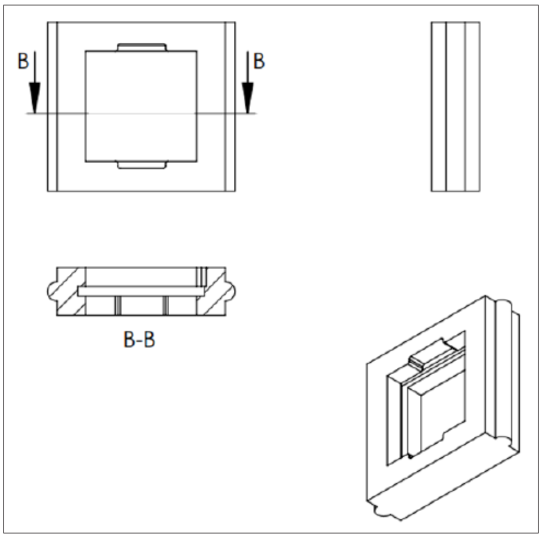

Figure 2: Sectional Cutaway View of the Sensor Sleeve

A flexible material was chosen to achieve a "click" mechanism with the rigid enclosure. Specifically, the material used is SMARTFIL by SMART MATERIALS, and it is the FLEX filament with a

Shore hardness of 93A. This elasticity allows the sleeve to function similar to those on mobile phones, adapting to the shape while remaining rigid.

The sensor sleeve was 3D printed following the manufacturer's recommendations for flexible filament, as this material requires specific printing parameters. Supports were used to create the internal cavities of the model, which were removed after printing using precision pliers.

• **Enclosure:** The enclosure was 3D printed with conventional settings using PLA, which is the easiest material to print. Supports were configured to achieve the detailed shape of the sensor sleeve compartment. In this case, supports were also necessary to print the internal cavities of the model. To save material, the piece was printed upside down, so the entire interior did not need to be filled with supports. The final result is shown in Figure 3.

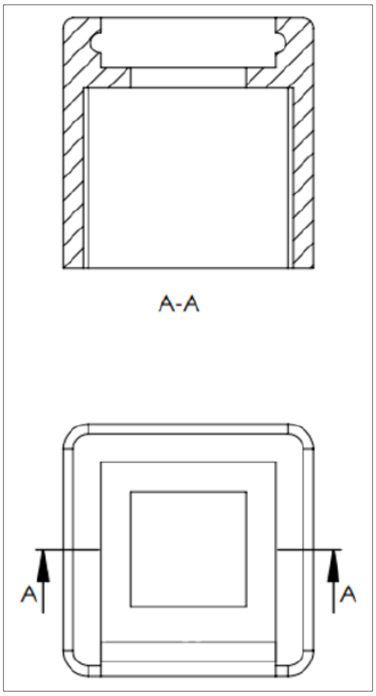

Figure 3: Sectional Cutaway View of the Sensor Enclosure

• **Sensor Back Cover:** It was necessary to design a back cover to prevent light from passing through the thinner sections of the sensor PCB. By using the same flexible material, a snap closure was achieved without any gaps, ensuring a complete seal (see Figure 4).

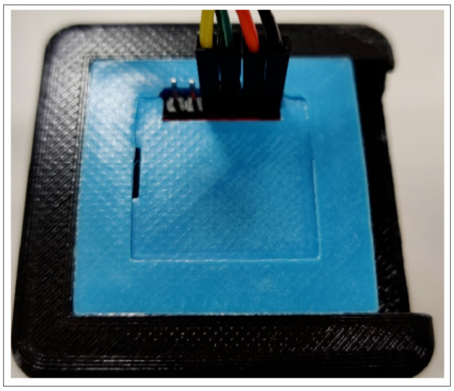

Figure 4: Sensor Installed in the Enclosure with Sleeve and Back Cover

• **Sample Carrier Plate:** Just as the design of the sensor enclosure is crucial to ensure optimal operation conditions, the plate on which the sample is placed is vital, as it must match the dimensions of the enclosure and ensure that the content is secure.

The function of the plate (see Figure 5) is to hold the sample to be measured on a specific surface that conforms to the shape of the sensor enclosure. It is designed to allow easy labeling on the palette for easy sample identification.

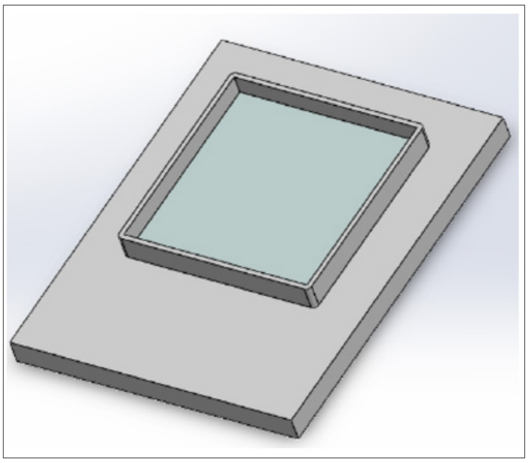

Figure 5: Sample Carrier Plate

Figure 6 shows the final assembly of the model as all components are brought together.

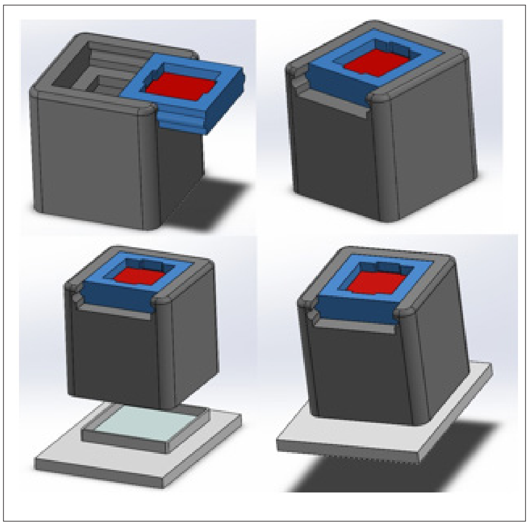

Figure 6: Prototype 1 Fully Assembled

B. Experiment 1: Analysis of Sensor-to-Sample Height Based on similar experiments conducted by other researchers, the experiment was replicated with the sensor acquired for this project [6]. This experiment aims to determine the influence of the height between the sample and the sensor when performing measurements.

The experiment involved taking successive measurements with the AS7263 sensor (Spark Fun), varying the height at which the sensor was positioned above the sample. To achieve this, three boxes were designed on which the sensor could be mounted, allowing for sensor interchangeability between boxes thanks to the developed mechanical base. The boxes only differed in height.

The first box brings the sensor closest to the sample. Figure 7 shows the most relevant views of this first piece. The separation distance is 1 mm, as indicated by the dimension, which is the minimum thickness of the material required to ensure the sleeve's attachment to the box.

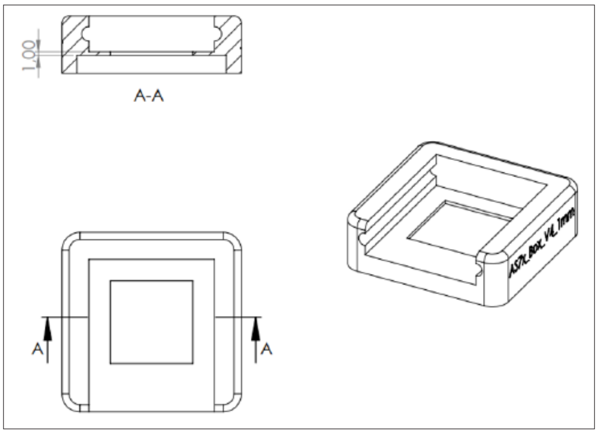

Figure 7: Prototype 1 Design Adapted to the Minimum Height

The second piece, shown in Figure 8, can be considered an intermediate phase between the original and the smallest box. In this case, the height is 2 cm.

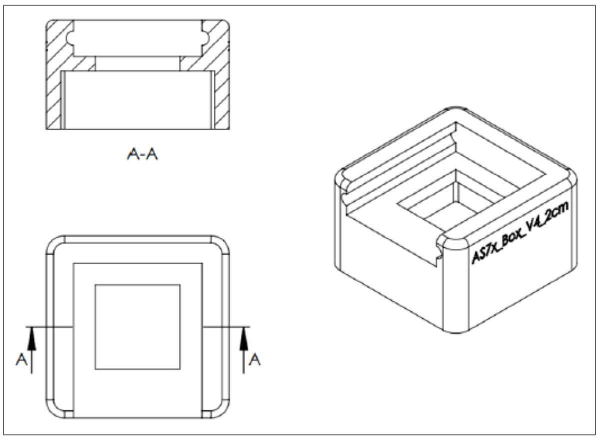

Figure 8: Prototype 1 Design Adapted to Medium Height

Once the pieces were designed, they were 3D printed, and sample readings were started with them. The result of printing the 3 boxes is shown in Illustration 9.

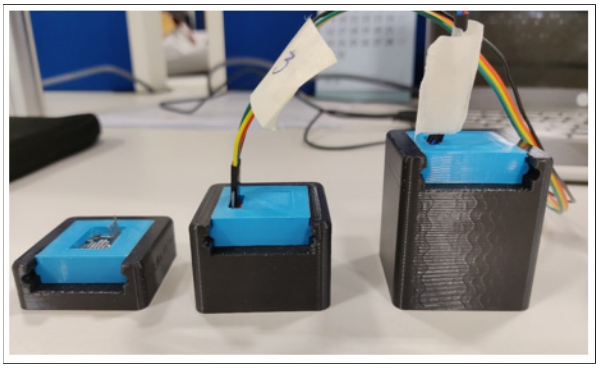

Figure 9: Result of Printing the 3 Boxes

For the measurements, the same time frame was used to avoid environmental conditions from altering the results. The same sample, a sheet of paper, and two types of flour were used for comparison, as these are the samples the sensor will encounter in its regular operation. The experiment was conducted using the same sensor to avoid alterations due to imperfections in the sensor's manufacture and minimize errors accordingly.

The following measurements were taken:

- 10 paper samples with the 36 mm sensor case.
- 10 paper samples with the 1 mm sensor case.
- 10 h6 flour samples with the 36 mm sensor case.
- 10 h6 flour samples with the 1 mm sensor case.
- 10 h2 flour samples with the 36 mm sensor case.
- 10 h2 flour samples with the 1 mm sensor case.

After analyzing the data using Pandas in Python notebooks, the generated graphs are shown in Figures 10 and 11.

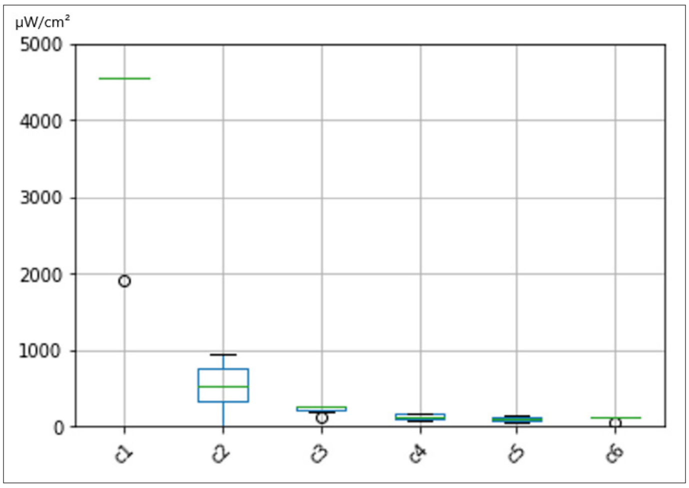

Figure 10: Candlestick Chart for the 1 mm Box for Channels 1 to 6 (c1- c6).

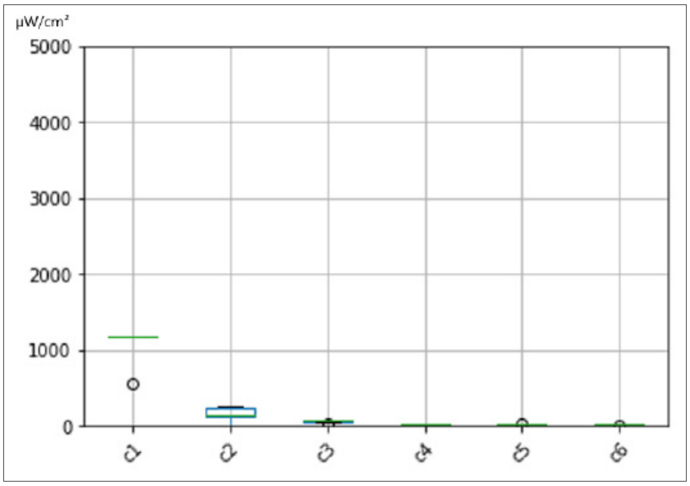

Figure 11: Candlestick Chart for the 36 mm Box for Channels 1 to 6 (c1- c6).

As can be seen from the generated graphs, for all cases, the power value captured per unit area is higher for the smaller box. This indicates that the further the sensor is from the sample, the more power is lost, which suggests that higher height leads to poorer resolution.

Despite the increased data dispersion in the readings with lower height, the values are precise. The lower deviation between the data for the 36 mm box can be justified by the loss of data caused by the mentioned power loss in the previous conclusion.

In conclusion, thanks to this experiment, it can be affirmed that the proximity of the sensor to the sample was crucial to achieve accurate readings and, therefore, the most representative data.

C. **Experiment 2:** Analysis of the Influence of Natural Light
Another variable that affects the measurement response is light. The sensor itself irradiates the sample with light and measures the sample's response to it. Knowing this, it can be inferred that if the sample is not always subjected to the same light, the results will differ. These variations may arise from ambient light since brightness changes depending on the time and day. Therefore, an experiment has been conducted to confirm this theory. Previous studies have already warned about the influence of light on measurements, but not specifically about the effect of ambient light [6].

First, a new box was designed based on the original design. This new model (see Figure 12) has a series of windows that allow light to enter the interior of the cavity, with the sole purpose of ensuring the height.

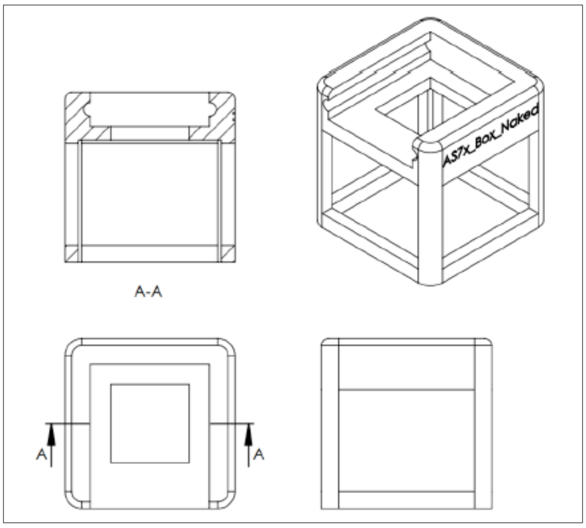

Figure 12: Box Design with Windows

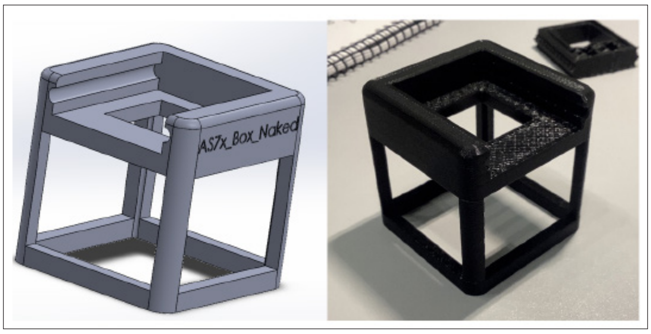

Figure 13: Design vs. Implementation of the Box with Windows

Subsequently, measurements of a paper sample were taken in environments with different luminosities (see Figure 14), comparing the results between the box that allows light entry and the original box. For each different environment, 20 samples were taken with a period of 1 second. The same sensor was used throughout the experiment, switching it between the two boxes for each environment.

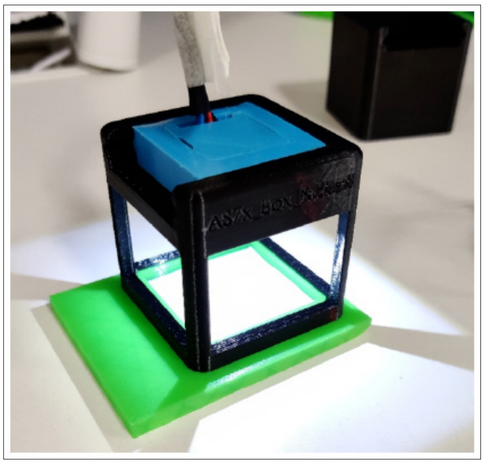

Figure 14: Execution of the Experiment

Once the measurements were taken, the data was analyzed using Pandas (Python), and the corresponding graphs were generated.

A data modeling for channel 1 is shown through a histogram (see Figure 15). It was performed only for channel 1 since it presented the highest dispersion of results in previous tests. As can be observed, for the set of experiments in the closed box, the values are concentrated within a specific range, except for some outliers in the initial range. On the other hand, for the set of tests in the open box, the data is much more dispersed, and the concentration lies in different bands compared to the closed box test. This indicates low repeatability for measurements made in an environment with natural or irregular light.

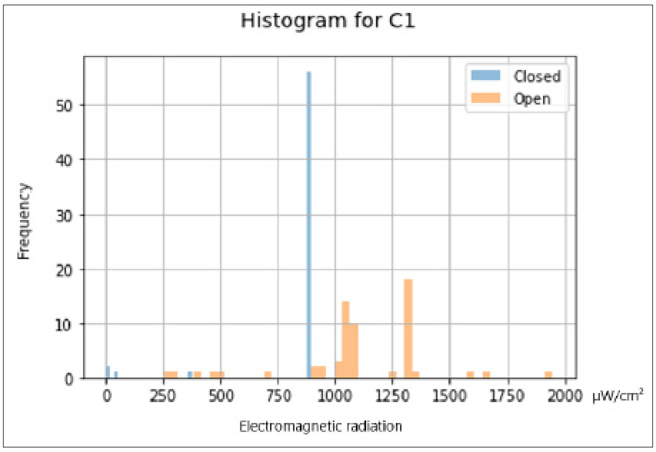

Figure 15: Histogram of Measurements for Both Environments for Channel 1

In conclusion, the desired results of the measurements require maximum repeatability, so that the data is reliable and of high quality. Therefore, the boxes or environments in which the sensor operates must be closed, avoiding contact with the external environment.

D. Experiment 3: Influence of Sample Preparation on Measurements
One of the advantages of the NIR sensor is that it does not require sample preparation. This means that it is not necessary to prepare a sample solution with chemicals to use the tool. However, the specific characteristics that the material to be analyzed must have have not been detailed, that is, how it should be presented to the sensor for correct measurement.

Given this uncertainty, an experiment was carried out to analyze the effect of sample presentation to the sensor. Specifically, the effect of pressing the flour during measurements was compared to the values of measurements without pressing. The decision to press the sample was made to replicate a previous study, but in this case, a specific presser was designed for this purpose [6].

The procedure was iterated a total of 6 times (one iteration per available flour sample at the time of the experiment), which consisted of the steps shown in Figure 16.

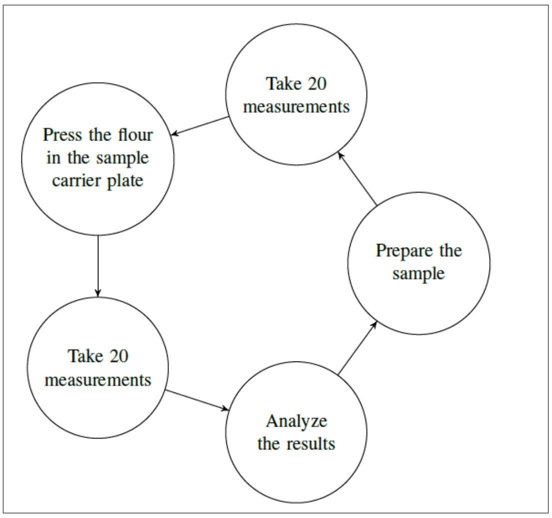

Figure 16: Diagram of the Iterative Cycle of the Experimental Process

The process of pressing the flour in the sample is shown in Figure 17, before and after the pressing.

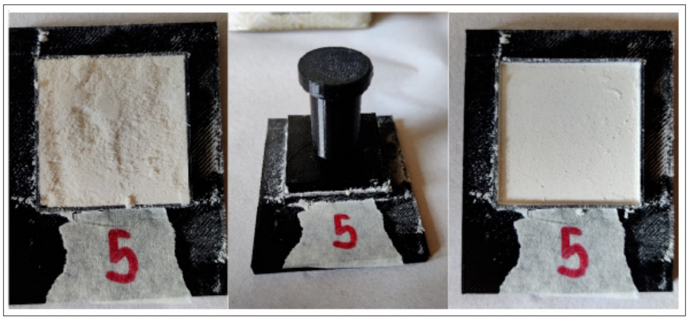

Figure 17: Flour pressing process.

The data for channel 1 was graphically presented in a histogram (see Figure 18). It was only performed for channel 1 as it showed the highest dispersion of results in previous tests. As can be observed, for the set of experiments with the unpressed sample, the values are concentrated within a specific range, except for some outliers at the beginning of the range. On the contrary, for the set of tests with the pressed sample, the data is much more dispersed, and the concentration lies in different ranges compared to the unpressed sample test. This indicates low repeatability for measurements made with a pressed sample.

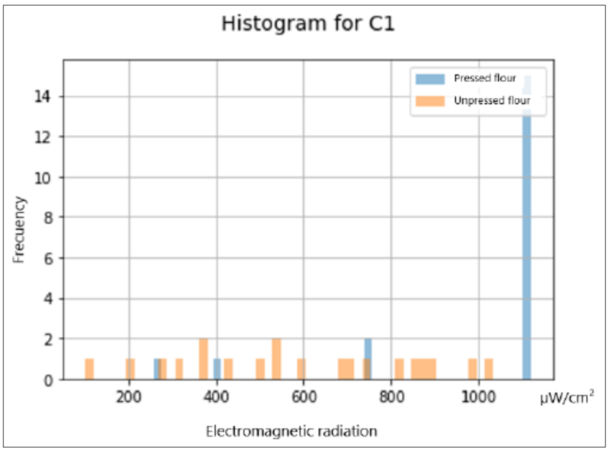

Figure 18: Histogram of Measurements with and without Sample Pressing for Channel 1

In conclusion, the preparation of the sample significantly affects the measurements. For reliable and accurate results, it is essential to ensure consistent and uniform sample preparation, avoiding pressing or altering the sample before taking measurements.

E. Prototype 2

The first prototype was designed for sensors from the Spark Fun family. Now, the design and implementation of Prototype 2 for the DLP NIR scan Nano sensor are shown. This professional sensor covers a broader spectrum range, necessary to detect gluten in the available samples. The design of this prototype takes into account the conclusions found in the performed experiments. The mechanical design has undergone significant changes since the anatomy of the sensor demanded it.

The design concept follows the same approach as Prototype 1: first, design a system that holds the sensor and then design another system that holds the previous part. This time, the connection between the two parts is made through a hinge.

The design has prioritized simplicity, avoiding confusion during its use. The degrees of freedom have been reduced to guide the user in the correct usage. This approach prevents misunderstandings and simplifies its operation.

The "Design for All" philosophy is applied. Universal design is a new concept that focuses on developing products that are easy to access for the largest number of people. The idea is not to redesign models, but to design them without barriers and accessible to all users, with or without disabilities. This philosophy covers all aspects of accessibility and is aimed at people with and without disabilities. The purpose is to simplify tasks by designing products and environments that are easy to use by all people effortlessly, benefiting all users [7].

Around 10% of the Spanish population has some form of disability. The most common disabilities among them are related to bones and joints (39.3%), hearing (23.8%), vision (21%), and mental health (19%) [8].

For the inclusion of these disabled individuals from the electronic perspective, a "closed" design has been considered, meaning that it cannot be used incorrectly even if someone tries. For this purpose, the two main components of the design (sensor and embedded system) have been joined together using a hinge, limiting their movement. The placement of the third part, the sensor plate, is delimited by grooves in the embedded system box.

Visually, to increase the intuitiveness of the product's usage, the parts have been designed with different colors to identify each color with a different body. This helps users understand that these parts move. The movements are specified through arrows to show the direction. This has been added after validating the device.

Additionally, LEDs with red and green colors have been installed. Red is used to indicate danger (contaminated sample), and green is used to indicate the opposite, as it is universally known. A buzzer has also been added to support the visual response.

1) Sensor Housing: The sensor encapsulation has the primary function of holding it in a fixed position and adapting its contour to that of the sample plate. It also has a cavity to incorporate the hinge that will later connect it to the box containing the embedded system. Additionally, a cover has been designed to cover the hole through which the sensor is inserted.

2) Embedded System Box: The box for the embedded system is responsible for storing the Raspberry Pi 4. It has holes for connecting power and peripherals (keyboard, mouse, and screen). The box consists of a body and a lid. The lid is responsible for positioning the sample plate in the appropriate position through rails.

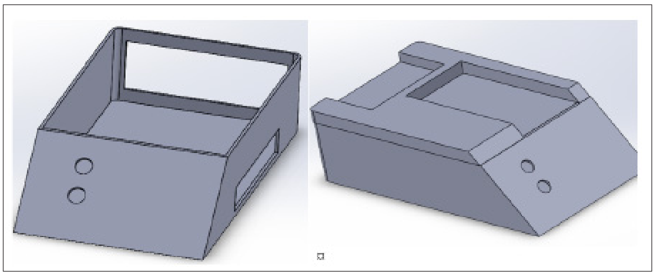

Figure 19: Embedded System Box with and without the Lid

As shown in Figure 19, the box also has a hole to insert the hinge, as well as two perforations to insert LEDs. These LEDs are placed on the diagonal plane for easy visualization by the user. The cavity beneath the plane containing the LEDs is used to gather the component cables.

3) **Final Assembly:** Figures 20 and 21 show the final assembly in different positions, with representative colors.

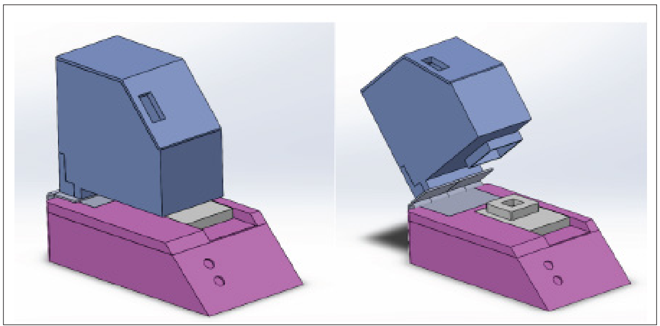

Figure 20: Prototype 2 performing a measurement and changing the sample plate.

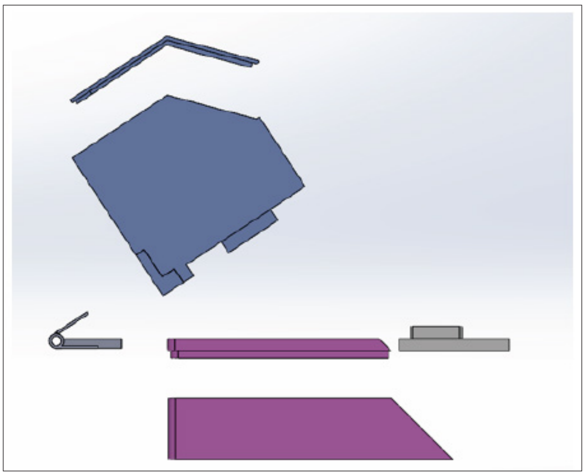

Figure 21: Exploded View of Prototype 2 Assembly

Figures 22 and 23 show the final implemented prototype.

Figure 22: Final Result of Prototype 2

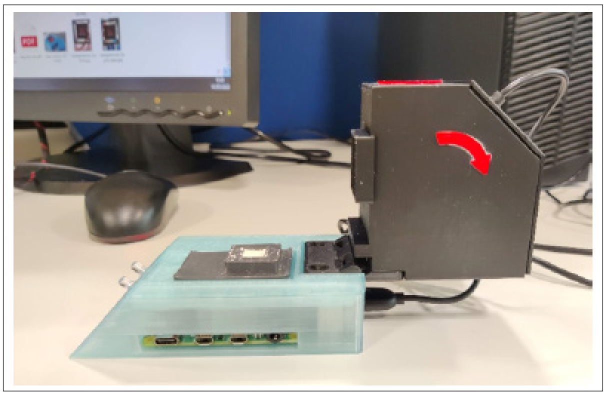

Figure 23: Prototype in the Process of Changing the Sample

F. Validation

Validation tests were conducted with a group of 7 potential users to assess the usability and accessibility of the implemented device. Before the test, the evaluators were briefed on the available alternatives to the device. The test was conducted with one celiac person, while the other users put themselves in their place to perform the exercise.

The test consisted of two forms: "Software Usability Scale (SUS)" and "USE Questionnaire: Usefulness, Satisfaction, and Ease of Use." Both tests have closed-ended questions, with the first being answered with values from 1 to 5 and the second with values from 1 to 7. In both cases, the minimum score means completely disagree, while the maximum score indicates completely agree.

First, the users were instructed on how to use the device. Then, they were allowed to manipulate the physical device to practice preparing samples and positioning them in the device. Finally, the users completed the questionnaire.

The following observations were extracted from the forms:

• Sample preparation
- The sample presentation or preparation part may be slightly inconvenient at first, as it requires some technique.
- Users agree that once they gain some practice, it becomes straightforward to prepare the sample. However, to acquire the skill, a good user manual is necessary.
- Users who may struggle with manual skills are those who are more advanced in age.

• Device
- It is easy to learn how to use and remember its use.
- Skill is quickly gained.

• General satisfaction is very positive, highlighting the usefulness and user satisfaction with the prototype.

Discussion

The present study has culminated in a successful design of a device for real-time gluten detection in food samples, employing the innovative use of NIR technology. Although the current blueprint proves to be competent, several user suggestions pinpoint areas where the design can further be refined. Adding directional indicators, such as arrows on the device (refer to Figures 22 and 23), could facilitate easier user operation, enhancing the device's value without incurring additional costs.

A prominent area that warrants attention is the sample preparation process. Users have found the initial encounter with the procedure somewhat laborious, emphasizing the necessity of a more streamlined approach. Creating an explanatory video to accompany the written instructions is a viable option to consider. However, developing a mechanical system to automate the sample preparation process promises to be a more effective solution, potentially enhancing the ease- of-use score observed in the tests. This concept forms a critical pathway in the projected future developments for this project. Remarkably, this research finds itself in a unique position, as there are no comparable studies analyzing the mechanical design of a comprehensive solution using NIR technology applied to food analysis, placing this work at the forefront of this scientific domain. Furthermore, the consideration of the device's size has been meticulously addressed in this study. Yet, its current design depends on a steady power source, highlighting the need for future integrations of wiring, battery systems, and possibly solar power options, facilitating more portable and versatile applications.

Moreover, a deeper investigation into the selected materials is warranted, given that the PLA, while being environmentally friendly and cost-effective, is biodegradable and may deteriorate over time [9]. Future research should explore durable alternatives that retain the device's green footprint.

The implications of this research are substantial, presenting opportunities to employ the device in personal settings, where individuals can utilize it to verify the safety of food at home, and in industrial environments for checking contamination in raw materials or monitoring the production chain. The device stands as a potential game-changer, offering a low-cost and user-friendly alternative to traditional methods, making it an excellent candidate for deployment in developing countries, where the budget or capabilities for food contamination analysis in laboratories are limited.

In summary, this study has paved a significant path in gluten detection research, showcasing a cost-effective, efficient, and innovative solution. The developed device not only aligns with the "design for all" philosophy but also represents a step towards democratizing health and safety measures, potentially transforming global approaches to food safety and quality control.

Conclusion

This research pioneers the focused development of a mechanical design that encapsulates NIR sensors, thereby crafting a user-friendly and sustainable tool capable of detecting gluten in food samples. It marks a big step, being the inaugural study to concentrate on the mechanical aspect of such encapsulation, targeting usability across a diverse user base and promoting environmental sustainability.

The inception and validation of a low-cost, portable mechanical device for gluten detection have been successfully achieved, fulfilling the ambitious objectives outlined at the beginning of this project. By honing in on the environmental conditions essential for precise measurements and assimilating the sensors within a sealed, opaque enclosure, a functional and validated final design has been realized. The imperative of sample preparation as a prerequisite for acquiring quality data stands as a vital discovery made during this research, steering future directions of this study.

The devised mechanical setup has demonstrated remarkable efficacy, having been successfully implemented in other research avenues concerning gluten detection. It transcends the constraints typically associated with conventional approaches, unveiling a pathway to a more efficient and economical alternative. The incorporation of 3D printed PLA materials has been instrumental in crafting a prototype that aligns with the green and sustainable objectives, delineating the feasibility of harmonizing technological advancements with ecological considerations.

Moreover, the usability of the device has been substantiated through SUS and USE evaluations, corroborating its accessibility and ease of use for a broad spectrum of users. This not only makes strides in facilitating quick and non- invasive gluten assessment in food for individuals with gluten intolerance but also lays a robust foundation for further explorations and advancements in the sectors of biomedical engineering and allergen detection in food products.

In conclusion, this work unfolds a new horizon in the field of gluten detection, presenting a tangible and economically viable solution that holds the potential to revolutionize personal and industrial approaches to food safety and allergen-- management.

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