TECHNICAL UNIVERSITY OF CLUJ-NAPOCA

ACTA TECHNICA NAPOCENSIS

Series: Applied Mathematics, Mechanics, and Engineering
Vol. 64, Issue Special IV, December, 2021

COMPETITIVE DESIGN AND PROTOTYPING OF A MEDICAL DEVICE USED FOR REDUCING THE SPREAD OF COVID-19

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Abstract: *This paper presents the design and prototyping process of a medical device that helps reduce the spread of infection with the SARS-CoV-2 virus (COVID-19), by devising a strategy that combines elements from Design Thinking and Design For Six Sigma. The resulting working prototype was tested in real-life conditions and no major functioning issues were recorded.*
Key words: *CODIV-19 preventing medical device, Design Thinking, Design For Six Sigma, 3D printing*

1. INTRODUCTION

Medical devices have been around for millennia, their purpose being to "diagnose, prevent, monitor, predict, prognose, treat or alleviate disease" [1]. The earliest medical device ever discovered was a tooth-drilling device, dating from 7,500-9,000 years ago, found in modern day Pakistan [2].

Since then, medical devices have come a long way, nowadays, "any instrument, software, appliance, implant or other article" [1] can be considered a medical device, if it is used for the previously stated purpose.

Their indispensability comes into focus especially during a pandemic, they are employed either to treat patients or to keep (limit) the infections rate under control.

Since 2019, the COVID-19 pandemic took and/or affected many lives and it doesn't seem that it will be over soon. In this context, medical devices that can lower the risk of getting infected or "alleviate"/fight the disease, by various innovative solutions, either simpler or more complex, are always welcome.

The aim of this paper is to develop a medical device that can lower the risk of infection with the SARS-CoV-2 virus, by measuring the temperature of individuals (which is considered by the World Health Organization [3] a symptom of the COVID-19 disease. If the temperature exceeds 37.3° C) and by limiting the number of people entering a closed space (according to [3] the recommended social distancing should be kept at 1 m or more, thus the number of people in that space should be carefully monitored to avoid over crowdedness). The device's design, development and finally its prototype creation was completed by applying a strategy that combines two well-known new product development methodologies: Design Thinking and Design For Six Sigma. Thus, the resulted product development strategy comprised the following stages and it included the instruments presented in Fig. 1:

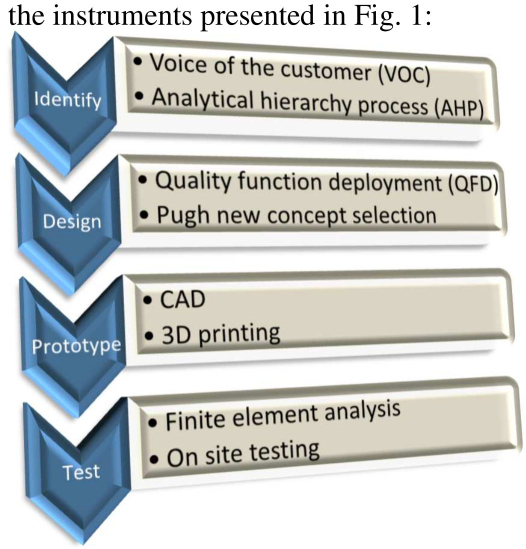


Fig. 1. Device's development strategy

2. DESIGNING, DEVELOPING AND PROTOYPING THE DEVICE

The process described in this section was based on the product development strategy presented in Fig. 1. In its first step, "**Identify**", a technique called "Voice of the customer" (VOC) was applied, followed by a prioritization instrument, "Analytical Hierarchy Process" (AHP). The former one helps identify which are the main requirements that the device should fulfill regarding multiple aspects, such as installation, accessibility, reliability and overall performance, while the latter one prioritizes those requirements to separate critical (very important) ones from the others. By doing so, the emphasis throughout the design process falls onto meeting the critical needs (with high importance percentage), which must be incorporated into the device.

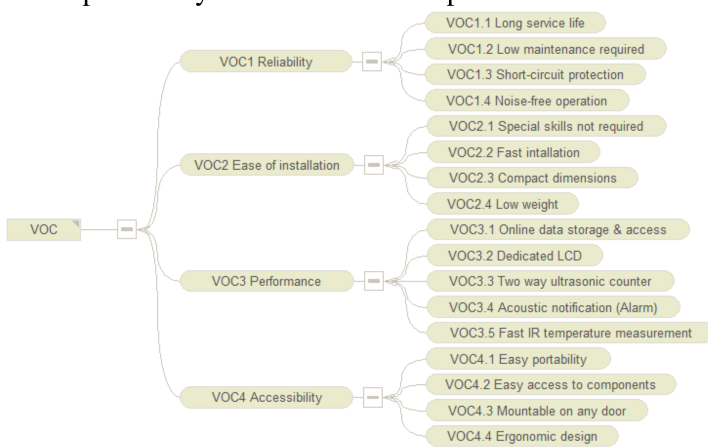


Fig. 2. VOC main categories and their constituents

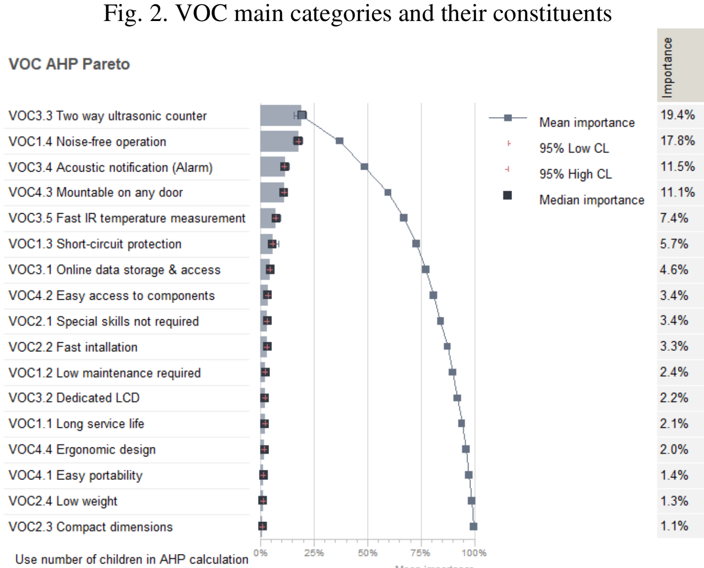


Fig. 3. Sorted results obtained from the AHP matrices

Fig. 2 and Fig. 3 showcase the application of the above-mentioned instruments in a dedicated software called Qualica 19 (Product version 6.5.2.3226 – 11.09.2021). As it can be seen, to keep the requirements in a more manageable form, they were grouped into categories, thus obtaining an "Affinity diagram"-type representation. It should also be noted that the AHP technique was divided into several matrices (instead of using one single matrix) to facilitate a more precise, correct and easy comparison between the requirements: first a global comparison matrix was devised, in which only the categories were compared to each other, after which the constituents of each category were compared amongst each other, separately. The consistency ratio was kept below 0.1 in all cases, assuring a low subjectivity, when filling out the AHP matrices [4],[5]. Finally, a compensation was applied, taking into consideration the importance of each category and in Fig. 3 the relative importance of each requirement can be observed, expressed in percentage.

The second stage, “**Design**”, comprised of devising (in the Qualica 19 software) the well-known “House of Quality” (QFD matrix) [6], in which, among other aspects, the requirements were compared against the technical characteristics (critical-to-quality – CTQs) of the device to verify to correlation between them. Doing so, it was assured that all identified requirements will be incorporated into the device’s design. The “House of Quality” (HoQ) included also two benchmarking analyzes (a requirements and a technical benchmarking – right side and bottom side of Fig. 4) [7], in which the designed device was compared to other similar ones existing on the market. An overview of the entire “House of Quality” matrix is illustrated in Fig. 4.

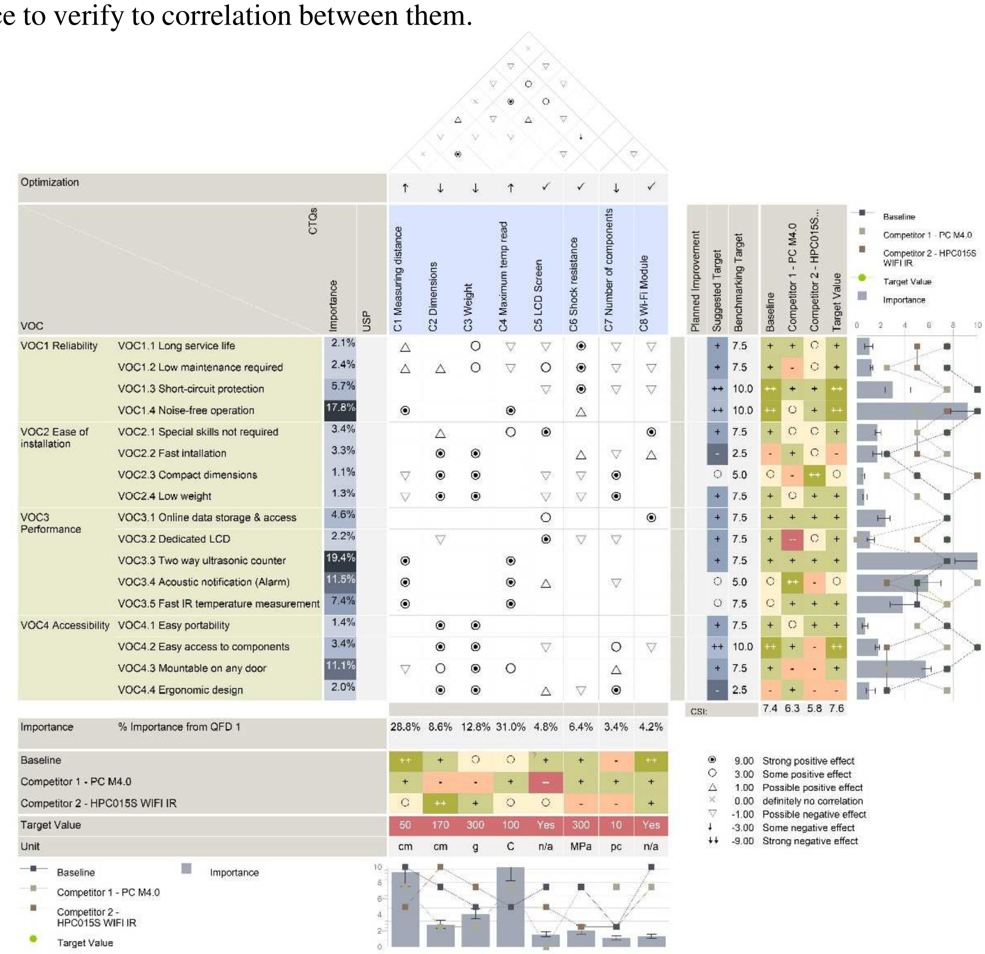


Fig. 4. House of Quality

After completing the HoQ, the CAD design process can take place, taking into consideration all the results obtained so far. In this sense, there were three constructive variants created, using the CATIA V5-6R2019 software, each with their own functional advantages and limitations, shown in Fig. 5. To assure that out of the three variants the best one is selected, a tool called “Pugh new concept selection” was deployed [8], in which all the variants are compared against defined criteria, in this case the requirements presented in Fig. **6**.

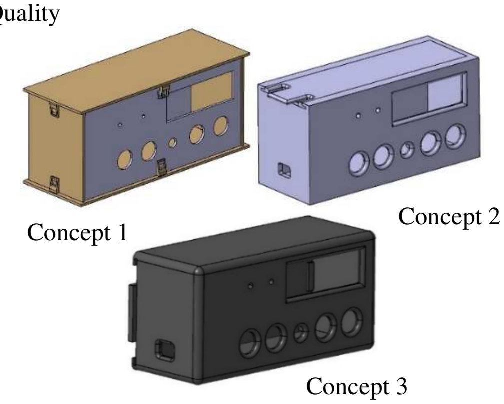
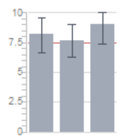


Fig. 5. Constructive variants for the device

--	0.00	Unacceptable
-	2.50	Borderline
O	5.00	Almost meets requirement
+	7.50	Meets requirement
++	10.00	Exceeds requirement

		Importance	Concept 1	Concept 2	Concept 3
Reliability	Long service life	2.1%	++	+	++
	Low maintenance required	2.4%	O	+	+
	Short-circuit protection	5.7%	+	++	++
	Noise-free operation	17.8%	+	++	++
Ease of insta...	Special skills not required	3.4%	++	+	++
	Fast intallation	3.3%	-	+	++
	Compact dimensions	1.1%	O	+	++
	Low weight	1.3%	+	++	++
Performance	Online data storage & access	4.6%	+	+	+
	Dedicated LCD	2.2%	++	++	++
	Two way ultrasonic counter	19.4%	++	+	++
	Acoustic notification (Alarm)	11.5%	++	-	+
	Fast IR temperature measurem...	7.4%	+	+	+
Accessibility	Easy portability	1.4%	++	++	++
	Easy access to components	3.4%	O	+	++
	Mountable on any door	11.1%	+	+	+
	Ergonomic design	2.0%	+	+	+



Weighted Score (0..10)	8.2	7.6	9.0
Not acceptable (VOC)			

Fig. 6. Pugh matrix for concept selection

As it can be seen in Fig. 6, all the three concepts meet the requirements, however, concept 3 has the highest compliance with the requirements, obtaining the highest score, out of the three constructive variants.

Another important aspect concerning the device's design is related to its internal hardware components. In this sense, another software tool was used (Fritzing v.0.9.6) to design the electrical circuits that contains 1 ESP-32 module (having also wireless connectivity), 2 ultrasonic sensors, 1 LCD + the I2C module, 1 IR thermometer, 2 LEDs. An example of such an electrical circuit is presented in Fig. 7.

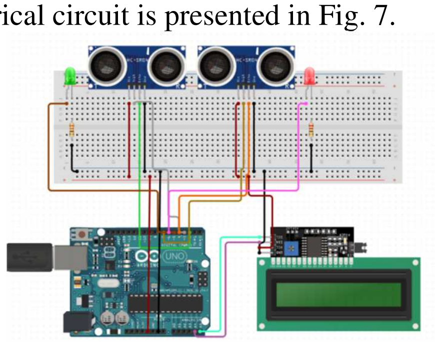


Fig. 7. Electrical circuit for 2 ultrasonic sensors and LCD

After the final design variant was selected and the internal hardware's layout was finalized, the "**Prototyping**" stage begun. The resulting model was converted to a *.stl format (standard triangulation language format), compatible with the 3D printer's software (Prusa Slicer v.2.3.3 – Fig. 8), which generates the "G" code containing all the printing instructions necessary to create the prototype. The 3D printer's make and model is Prusa i3 mk3s+ and the main printing parameters were: material Φ1.75mm PLA, 0.2mm resolution, 25% infill, estimated printing time ~12h50min, 143g weight.

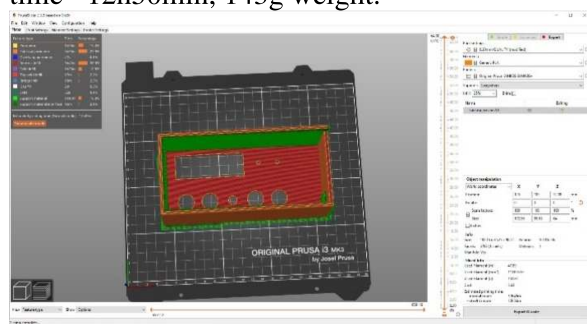


Fig. 8. Slicing the 3D model

The "**Testing**" stage comprised of two types of methods: conducting finite elements analysis in the CATIA V5-6R2019 software, to determine whether the case of the device can withstand shocks resulted from manipulation, installation and/or accidental drops (virtual testing – Fig. 9) and secondly, the device was also tested on site, in real-life conditions in one of the Technical University of Cluj-Napoca's locations (103-105 Muncii Blvd., Cluj-Napoca, Romania – Fig. 10).

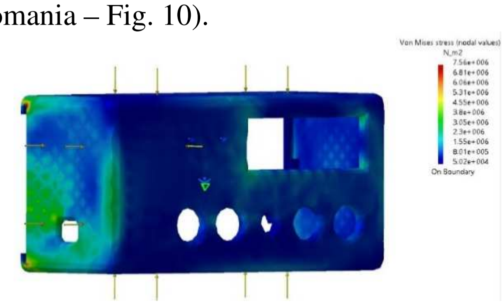


Fig. 9. Finite element analysis of the device's case

As it can be seen from the analysis illustrated above, the device's case should withstand a stress resulted from the application of 100 N (about 10 kgf) on the case's surface.

The onsite testing was completed within the May-July 2021 period, when the Technical University of Cluj-Napoca resumed its onsite educational activities and students came to defend their bachelor or dissertation theses on site.

Fig. 10. Installing the device on site

The testing didn't reveal any major issues regarding the device's functioning, however, in some cases, when the distance between the subject and the device exceeded 50 cm the temperature measurement wasn't exact, in the sense that the sensor returned abnormally low values. This issue was solved by recalibrating the temperature (IR) sensor's range and carefully repositioning/remounting the device on the door frame.

3. RESULTS

There are three main elements that should be discussed when referring to the device's prototype: the case's design, the design of the hardware components and electrical circuits and the programming of the software, based on which the device functions.

The inner components of the device are showcased in Fig. 11, and as stated in the previous section they were configured using the Fritzing v.0.9.6 software program.

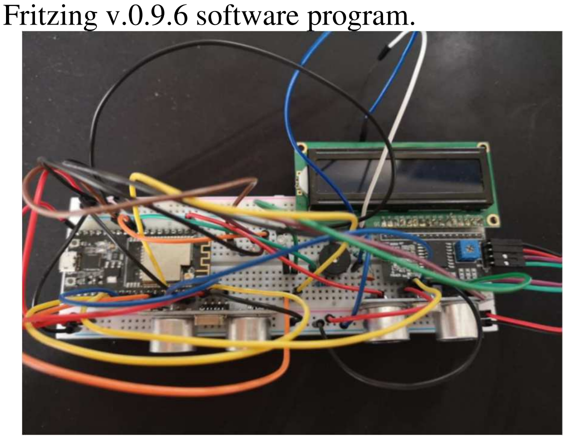


Fig. 11. The device's hardware components

The software for writing the code, that was uploaded to the motherboard, based on which the device functions, was the open-source Arduino IDE and it included about 200 lines.

The device's working prototype, with all the hardware components mounted inside, is illustrated in Fig. 12.

Fig. 12. The device's working prototype

Alongside the device's base code, an online platform was also created (Fig. 13), to which the device was linked (through its Wi-Fi connectivity module), thus enabling it to send online all the data that it measures. By doing so, one can check at any time how many people are currently within the monitored closed space and what was the maximum temperature recorded of the individuals that entered that space. The interface of the platform is minimalist, but the authors plan on adding other functions to it at a later point (e.g. statistics concerning the peak hours in a single day).

Fig. 13. The device's online platform

4. CONCLUSIONS

The current paper proposed the application of methodologies and dedicated tools mainly used in the field of competitive product design, which were deployed in the development and prototyping process of a medical device that helps prevent the infection with the SARS-CoV-2 virus (COVID-19), by counting the number of individuals entering a closed space (thus, enabling the limitation of people present in that location at any given point) and by measuring their body temperature.

The device was tested in real-life conditions in one of the locations of the Technical

University of Cluj-Napoca for several months and no major issues regarding its functioning were recorded.

The device is also linked with an online platform to which the measured values are sent, enabling real-time tracking of how many people are present in the monitored location and what was the max. temperature recorded.

Future development directions include refining the online platform to include other functions, as well, and fine tuning the design of the device, such that it can be installed also on public transportation vehicles.

5. ACKNOWLEDGMENT

This article has benefited from the support of the project 345PED/2020 "Smart hospital bed - HoPE" funded by the Executive Agency for Higher Education, Research, Development and Innovation Funding (UEFISCDI), Romania.

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PROIECTAREA COMPETITIVĂ ȘI PROTOTIPAREA UNUI DISPOZITIV MEDICAL UTILIZAT PENTRU REDUCEREA RĂSPÂDIRII COVID-19

Abstract: *Această lucrare prezintă procesul de proiectare şi prototipare a unui dispozitiv medical care ajută la reducerea răspândirii infecției cu virusul SARS-CoV-2 (COVID-19), prin conceperea unei strategii care combină elemente din Design Thinking şi Design For Six Sigma. Prototipul rezultat a fost testat în condiții reale și nu au fost înregistrate probleme majore de funcționare.*

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