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Design and Test of wPUM Topography Monitor for IQOS

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Master's Thesis

Design and Test of wPUM Topography Monitor for IQOS

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ABSTRACT

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With the emergence of diverse tobacco product forms, such as electronic cigarettes and heat-not-burn, the global user base has surged to an estimated 1.3 billion. In the United States, 28.3 million adults and 3.08 million middle and high school adolescents engage in tobacco product use. However, our understanding of the usage behaviors of these various products is lacking. Puff topography, which measures the inhalation patterns of tobacco products, provides a wealth of information, including puff flow rate, duration, volume, and more. This information is crucial in understanding the health effects of tobacco products and the influence of usage behavior on product performance. To ensure accurate and real-world results, it is vital to develop the capability to measure puff topography in the natural environment.

The Respiratory Technology Lab has designed several wireless topography monitors, called wPUM, for combustible cigarettes, hookah, and types of e-cigs. This thesis aims to rigorously apply the design process to develop an IQOS version of the wPUM topography monitor. This work will not only add a line of products to the existing family of wPUM monitors but also examine the existing product lines and articulate a product design framework that future designers can use. The hope is that this design framework will facilitate the rapid design of new wPUM monitors while maximizing creativity to meet the ever-changing tobacco product market.

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1 INTRODUCTION

1.1 SPECIFIC AIM

This thesis aims to rigorously apply the design process to develop an IQOS version of the wPUM topography monitor. This work will examine the existing product lines and articulate a product design framework that future designers can use. The framework will facilitate the rapid design of new wPUM monitors while maximizing creativity to meet the ever-changing tobacco product market.

1.2 TOBACCO PRODUCT USE IN THE US

1.2.1 Why Do People Use Tobacco?

Tobacco is mainly used for nicotine content, which is a highly addictive ingredient present in tobacco leaves. Nicotine is a stimulant with both enjoyable and soothing effects that differ from person to person. The reasons why people smoke are addiction to nicotine [1], stress relief [2], the belief that it contributes to weight control [3], social and peer pressure [4], adaptation mechanism [5], and cultural and historical traditions [6].

1.2.2 What is the Prevalence of Nicotine Addiction and Tobacco Product Use in the US?

The frequency of nicotine addiction varies by age, gender, and other characteristics in the United States. The National Survey on Drug Use and Health (NSDUH), conducted annually by the Substance Abuse and Mental Health Services Administration (SAMHSA), is the primary source for monitoring nicotine addiction [7].

It has been estimated that there are 1.3 billion tobacco smokers globally. In the United States, there are 28.3 million adults and 3.08 million middle and high school adolescents who use tobacco products [8]. Smoking prevalence has decreased over time due to public health efforts, awareness campaigns, and more robust tobacco control measures [9] [10]. In 2019, it was estimated that 50.6 million adults in the United States (20.8%) reported using any tobacco product, including cigarettes (14.0%), e-cigarettes (4.5%), cigars (3.6%), smokeless tobacco (2.4%), and pipes (1.0%) [10]. Young people's use of e-cigarettes has been on the rise, with a significant surge in the past few years named the “vaping epidemic” [11]. Smokeless tobacco products such as snuff and chewing tobacco are less popular than cigarette smoking. Around 3% of individuals reported using smokeless tobacco in 2019 [10].

It's worth mentioning that the nicotine addiction landscape has been changing with the introduction of new goods such as electronic cigarettes (e-cigarettes) and vaping devices [12]. These products have caused worries about nicotine addiction, particularly among young people. E-cigarette use is closely linked to the use of other tobacco products in adolescents and young adults. E-cigarette use has surged significantly, particularly among young people and adolescents [13]. Every day, over 1,600 U.S. young people under 18 years old smoke their first cigarette [14]. Public health organizations have implemented education, regulation, and cessation programs to address this issue [15].

1.2.3 Health Effects of Tobacco Use

Nicotine exposure has been linked with cognitive deficits, memory, and executive function impairment, though most of the severe health effects of tobacco use come from other chemicals [11]. About 16 million people suffer from a severe disease related to smoking [14].

CDC supports the idea that combustible cigarette smoking damages practically every organ of the body, producing different diseases and harming smokers' overall health [16]. Smoking can lead to lung cancer, chronic bronchitis, and emphysema. It increases the risk of heart disease, leading to stroke or heart attack [17]. Smoking, including hookah, has also been linked to other cancers, leukemia, cataracts, Type 2 Diabetes, and pneumonia [15]. Annually, more than 7 million smokers die from direct cigarette use [18].

In addition, there are well-known health hazards linked with secondhand smoking (SHS). Secondhand smoke, also known as passive smoke and environmental tobacco smoke (ETS), is a mix of air exhaled by a smoker and smoke generated by a tobacco product's smoldering ends [19]. There is no safe amount of time for exposure to nicotine [20]. Even a short period can cause severe problems or premature death from SHS. Secondhand smoke causes coronary heart disease, stroke, and lung cancer in adults who do not smoke [21]. In newborns and children, SHS can cause sudden infant death syndrome (SIDS), respiratory infections, ear infections, and asthma. In newborns and children, it can trigger asthma attacks and worsen the condition [21] [22]. Pregnant women smokers have a higher chance of miscarriage, stillbirth, early birth, or low birth weight babies [22].

Many countries and jurisdictions have adopted smoking prohibitions in public places, workplaces, and indoor locations to protect the health of nonsmokers due to the substantial health concerns connected with secondhand smoke. Public health initiatives raise awareness about SHS's dangers and encourage smoke-free surroundings [23]. The most effective strategy to remove the risks associated with SHS exposure for smokers and others is to quit smoking [24].

1.2.4 Trends in Tobacco Use Towards Safer Nicotine Delivery

The tobacco industry has trended toward marketing “safer” products. But are they “safer”? Hundreds of risky compounds are present in tobacco product smoke. There are around 7,000 compounds in cigarette aerosol, and approximately 70 can cause cancer [25]. Tobacco corporations have made multiple efforts to develop "safer cigarettes," such as "low-tar" cigarettes, electronic cigarettes, and heated tobacco products [26] to avoid combustion and produce a nicotine aerosol that the user inhales. It is widely assumed that e-cigarettes release less harmful chemicals than combustible cigarettes [27]. Even though e-cigarettes may contain fewer harmful toxins than cigarettes, their short- and long-term consequences are unknown.

1.2.5 The Goal of Tobacco Science Research in the US

Many agencies, national and international, are focused on tobacco product use and its effects on public health. The World Health Organization (WHO) has classified tobacco product use as an epidemic, posing the most severe public health hazard in history [18]. The Food and Drug Administration (FDA) supports science and research to help us better understand tobacco use and related dangers to reduce the death and disease caused by tobacco use in the United States [28] [29].

The FDA's Center for Tobacco Products (FDA/CTP) has the authority to regulate the manufacturing, distribution, and advertising of tobacco products. The FDA/CTP educates the public, particularly young adults, about tobacco products’ risks for themselves and others [30]. The United States National Institute of Health (NIH) has several agencies that support tobacco science research. For example, the National Institute on Drug Abuse (NIDA) has a goal to enhance science on drug use and addiction and to utilize that knowledge to improve both personal and public health, both clinically and socially [31]. This thesis aims to support these agencies' work by enhancing knowledge about usage behavior, specifically by designing puffing topography monitors to assess how people use inhaled tobacco products in their natural environment.

1.3 RIT’S RESPIRATORY TECHNOLOGIES LAB RESEARCH

The RTL's primary goal is to improve understanding of the "association between product characteristics, behavior, and health to guide effective treatment and regulatory policy." Our study technique assumes that interconnected and multi-directional pathways exist between tobacco product features and health impacts (as shown in the diagram). Our lab is unique in focusing on natural use behavior and pioneered ambulatory natural use topography technology.

Figure 1. Shows the Respiratory Technologies Lab (RTL) illustration of topics related to the nicotine delivery system study. It demonstrates the link between the various research approaches by focusing on Product Characteristics as the investigation's focal point and starting point. Different factors include consumption, topography, emissions, health effects, toxicity, and addiction.

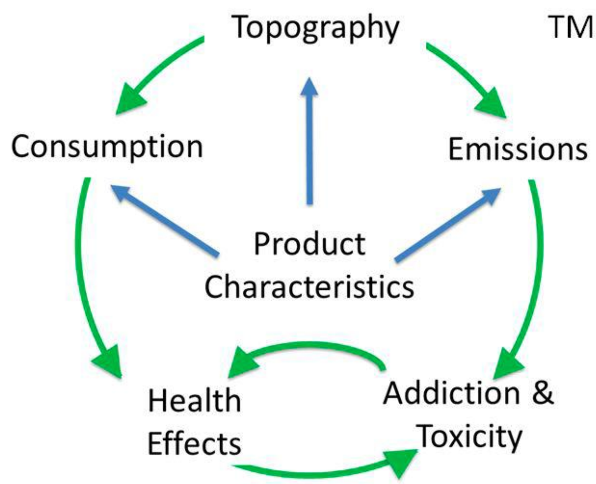


Figure 1. As proposed by the RTL, tobacco products research areas and their relationship with each other.

Nicotine delivery systems (combustible and non-combustible) have been studied from diverse perspectives. Some studies, for example, concentrate on the items' health impacts and toxicity, while others focus on emissions and chemical analyses.

Rochester Institute of Technology's Respiratory Technology Lab (RTL) proposed a study methodology that covers the various research areas connected to nicotine delivery methods within specific subjects and demonstrates their vital relationships. This framework includes product characteristics, topography, consumption, emissions, health effects, addiction, and toxicity.

1.4 What Is Topography?

Puffing (or puff) topography is the user behavior pattern when using inhaled nicotine products such as e-cigarettes or traditional combustible cigarettes. Puff topography parameters include puff flow rate, puff duration (PD), puff volume (PV), inter-puff interval (the time between individual puffs or IPI), and puff number during the assessment of puff topography**.** The average flow rate is determined by integrating all the instantaneous flow rate data over the puff duration. There is an instantaneous and average flow rate; the average flow rate is the mean of the instantaneous flow rate over the puff duration**.**

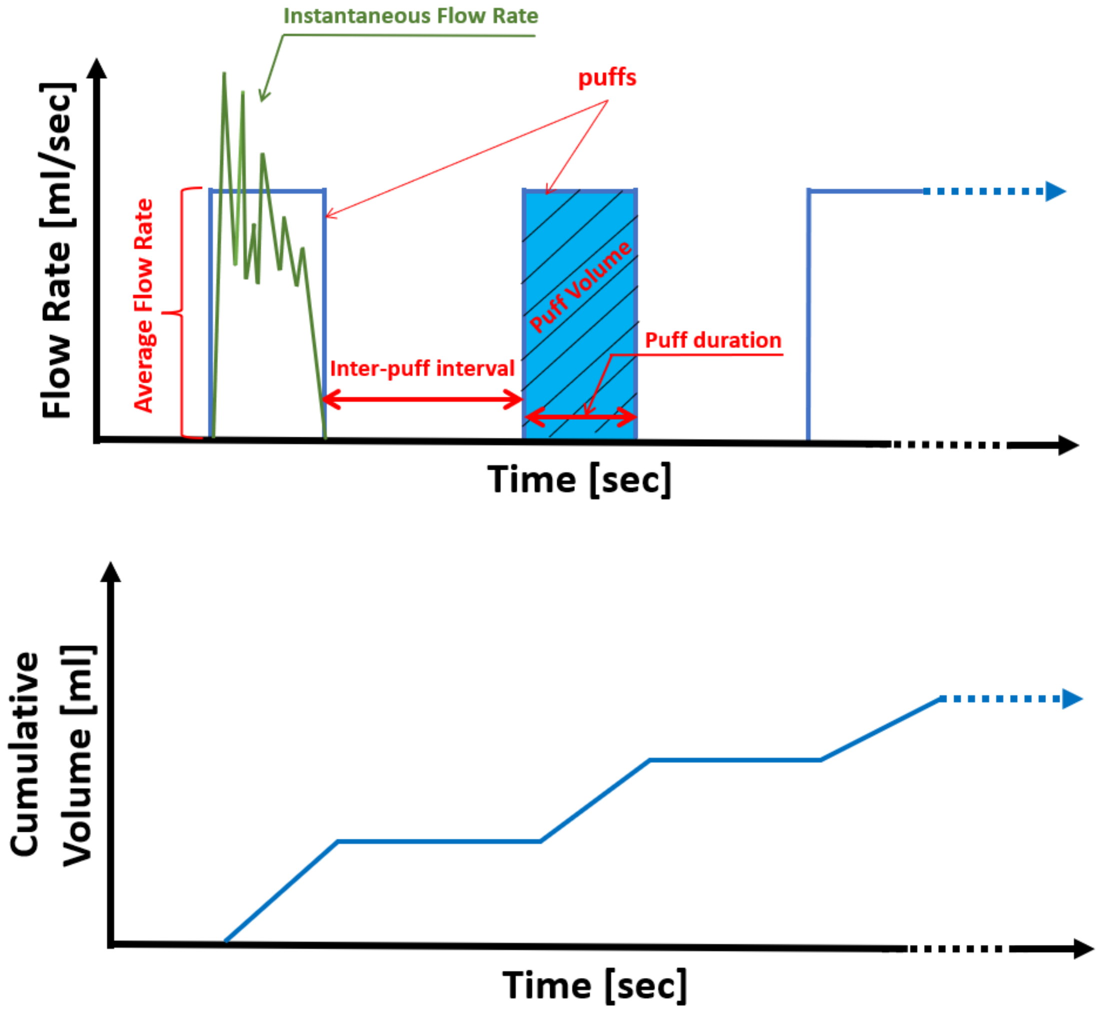


Figure 2. Illustration of puff topography parameters. The upper graph shows the instantaneous and mean puff flow rate, while the lower graph shows the cumulative volume.

1.4.1 Puff Versus Respiration Topography

Puff topography measures the aerosol flow contact between the flow of inhalants from the tobacco product to the user's **mouth**. Puff topography can be performed by using wPUM. Respiration topography measures inhalation flow rate and volume into and out of the user's **lungs.** Respiration topography can be achieved by monitoring the variations in lung capacity and chest motions [32]. This can be accomplished using a monitor chest movement types of equipment like chest straps and chest belts [33] [34] [35]. RTL uses the Hexoskin shown in **Figure 3.** Respiration topography includes normal tidal breathing and puff-associated respiration (PAR). PAR is the inhalation of clean air users take to move the tobacco aerosol from the mouth into the lungs.

Figure 3. Left panel: a person using an IQOS prototype for an RTL topography monitor to measure puff topography. Middle panel: a person modeling an RTL Hexoskin to measure inhalation topography. Right panel: PAR (puff–associated respirate versus tidal breathing) [35].

1.4.2 Ambulatory Versus In-lab Topography Measurements

Ambulatory means the smoker uses the device naturally while other laboratory tests occur. The situation and surrounding environment can affect tobacco product usage behavior. It was observed that the use behavior differs in the lab and the natural environment. Lopez-Meyer. et al. 2013 [36] have concluded that observing tobacco puffing and respiratory behavior in realistic situations is critical to obtaining the most accurate and valuable measurements of puffing and respiratory parameters. Several differences were found in results generated from in-lab and natural environment studies. For instance, smokers had higher heartbeats during the session in the lab compared to their natural environment [37]. An explanation of such difference could be that they felt embarrassed or under stress for asking them to smoke or not want to start smoking at that time [37]. Ambulatory assessment can help " fill in the blanks" about what happens in the real world and outside of the laboratory [38]. The information picked up by ambulatory calculation has the potential to contribute not just to the development of effective cessation therapies but also to the more considerable theoretical literature on smoking behavior and relapse [38].

1.4.3 Topography as an Integral Part of RTL Research

Puff topography is crucial to studying different aspects of tobacco product research, including projects employed at Respiratory Technology's lab. Wadkin et al.2022, [39] highlighted the importance of using realistic topography to drive puffing machines to generate natural emissions. Tobacco manufacturers traditionally report emissions from machines driven by artificial and unrealistic standardized topographies by The Federal Trade Commission and The International Organization for Standardization (FTC/ISO standards) [40, 41], which means unrealistic puffing durations, constant flow rates, and inter-puff intervals. RTL reported that these standardized topographies do not agree with natural environment topography [42]. However, those standardized parameters are still recommended according to ISO or the Cooperation Centre for Scientific Research on Tobacco (CORESTA) [39], and commercially available electronic vaping machines predefine the set of puffing parameters to collect the product's aerosol [39].

RTL discovered that tobacco product emissions varied as a function of the topography [43]. We will receive a dense cloud if we use an electronic cigarette at a high flow rate. We obtain two distinct cloud densities if we make that puff at two different flow rates. There are more emissions in the low flowrate puff than in the high. Robinson et al. 2020 reported that these yields do not emulate actual behavior [42]. Hensel et al. 2019 [44] proposed a framework to incorporate real-use topography into emissions testing. Hensel et al. 2021 [45], published emission studies on realistic topographies using data obtained using RTLs topography monitors.

Puff topography is essential to understanding aerosol behavior inside the lung. Aerosol particles interact with the walls of the internal air pathway through the lung in three mechanisms: sedimentation, impaction, and diffusion. These mechanisms depend on several factors, which are particle size, particle mass, and particle velocity. Puff topography is a key to determining particle velocity as they enter the air pathway. For example, if a user puffs quickly with a high flow rate, the aerosol particles enter the lungs faster than if the user puffs slowly with a low flow rate [46]. Higher flow rates for a given particle size will increase deposition by impaction and decrease deposition by sedimentation. Therefore, all mechanisms should be considered along with the actual flow rate of air in the user's lungs.

A recent RTL PhD dissertation focused on designing a Biomimetic Aerosol Exposure System (BAES) for toxicity studies [47]. This work aimed to provide a realistic flow to expose cells to natural conditions and accurate cues. BAES will achieve biological inspiration by replicating a human inhalation of an electronic cigarette by puffing and inhaling the surrounding air between puffs. Natural environment topography monitors provide the tools to collect data for BAES.

1.4.4 Literature Review of (Non-RTL) Topography Methods

More data describing realistic tobacco product use in the natural environment needs to be provided to guide the Food and Drug Administration (FDA) regulation policy. RTL realized the topography monitors available to purchase did not meet RTL's research needs. Commercially available topographical monitors have shown it to be challenging to capture topography and consumption data reliably, and they are incompatible with a wide range of alternative tobacco products, such as hookah and JUUL e-cigarettes [48].

In the earliest research, smokers were frequently questioned about how many cigarettes they smoked in a specific amount of time. They often find that the information from self-monitoring needs to be more precise. Although users' self-reported puffing behavior (the amount and interval between puffs) is somewhat accurate, they could not appropriately estimate their exposure to smoke or the intensity and density of their puffs [49]. Methods such as trained observation, flowmeters, pneumotachographs, pressure transducers, and video cameras are used to research smoking topography [50]. One of the simplest ways of assessing puff topography is video recording, which needs little expertise [51]. However, video cannot accurately measure all the parameters required to understand consumption, and the concept is unfeasible in real-world assessments due to the requirement for video devices.

Electronic puffing topography assessment devices offer greater accuracy and precision in measuring topography parameters, making them more acceptable for regulatory submissions. They can measure more parameters, including puff flow rate, than simple video or on-device recordings.

A topographical measurement instrument that is commercially available, the Clinical Research Support System (CReSS) Pocket device measures several e-cigarette parameters, including puff length, puff count, total volume, flow rate, peak flow rate, and inter-puff interval. It gathers information on the device, which may be downloaded by connecting to a PC. 3D printing is used to create adapters for different types of e-cigarettes; however, the connection method puts weight restrictions on the device [52]. Other limitations of the CReSS monitor include loss of data caused by device failure [53], inability to detect puffs with a flow rate of fewer than 20 ml/s, and puff duration of only 5 seconds [54]. In addition, the CReSS can record a puff count of 43 puffs [55] with a maximum operation duration of 20 minutes, making it unsuitable for natural environment studies. The SODIM Smoking Puff Analyzer

Mobile Device (SPA-M) is like the CReSS device used in studies to assess e-cigarette puff topography. In a study by Mikheev et al., the SPA-M device showed less variability than the CReSS device, possibly due to its higher sensitivity. Human data collected during at-home use was more accurate with the SPA-M device. However, the complicated software used for data analysis may affect the choice of device [56], [57]. Both devices can provide precise measurements only within specific puff parameter ranges, and to prevent erroneous data interpretation, both devices need a careful examination of the raw data. British American Tobacco has modified the Smoking Analyzer 7 (SA7) device to measure e-cigarette puff topography, measuring the duration and volume of machine-generated puffs across various e-cigarette types. The modified device also demonstrated applicability in assessing puffing behavior in a laboratory setting [55]. This monitor requires continuous connection to a computer, limiting its portability for ambulatory studies.

To overcome the weaknesses of the previous methods, the Respiratory Technology Lab (RTL) designed, built, and tested a wireless personal use monitor (wPUM) **Figure 3**. wPUM is a handheld device with a pressure sensor and sufficient electronics for data recording that attaches to the cigarette product or e-cig device. wPUM records puff topography, including parameters such as the flow rate, duration, and volume of each puff taken and the date and time.

In summary, improved topography monitors are needed to allow researchers to examine how users puff different products in their daily use history and total aerosol consumed in natural settings without interfering with their desire to use the monitor or consume their product.

Figure 4. The Smoking Puff Analyzer Monitor (SPA-M)

Figure 5. The Clinical Research Support System (CReSS)

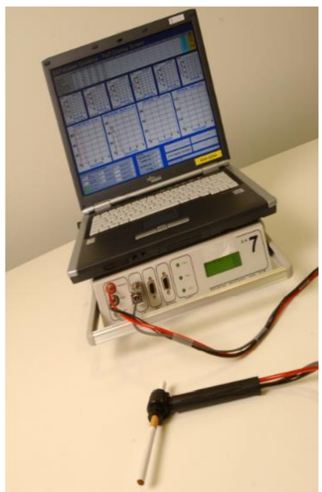


Figure 6. Smoking Analyzer 7 (SA7) from the website

1.5 WHAT IS IQOS?

1.5.1 General Description of IQOS, Including Who the Manufacturer is.

IQOS **pronounced: "eye-kose" or "eye-cus**", is a brand of Heated tobacco products (HTBs) that is considered an alternative to combustible cigarettes [58]. IQOS is a novel electronic nicotine delivery system (ENDS) manufactured by Philip Morris International (PMI). PMI is the parent corporation of numerous Philip Morris affiliates with over 175 markets worldwide [59]. Philip Morris International was the world's second-largest tobacco company in 2022. The headquarters are in Stamford, CT, USA, and the Operations Center is in Lausanne, Switzerland [60]. PMI, on their website, claimed that there has never been an acronym for IQOS [61]. While commercially, IQOS stands for "I Quit Ordinary Smoking", IQOS is also advertised as "cleaner", "smoke-free", and "only steam" [62]. IQOS has three parts: charger, device, and Heat Sticks **Figure 7.** The device is reusable and cleaned to prepare for the next session. The Heat sticks are consumable and sold separately.

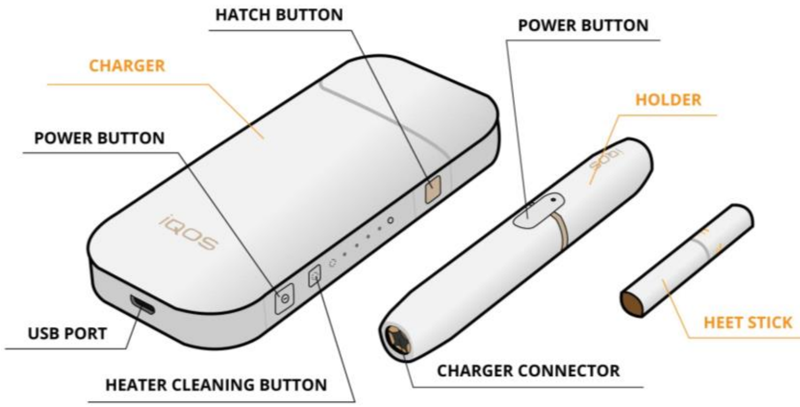


Figure 7. IQOS components with feature annotations [63].

1.5.2 How IQOS Operates to Produce an Aerosol

IQOS heats the tobacco sufficiently without combustion to make it smolder and create smoke without fire, ash, or smoke [64]This process produces an aerosol that the user inhales, giving them the same flavor and nicotine as traditional cigarettes. Firmware and a microcontroller electronically regulate the heater's temperature. The energy supply is shut off if the temperature rises above 350°C (350 degrees Celsius or 662 degrees Fahrenheit).

The heat stick is inserted into the proximal end of the device and heated with the metal piece within the device called the heating electronic blade, also called the 'heater' **Figure 8.** This releases the flavor of heated tobacco and creates a tasty vapor that contains nicotine [64]. This process happens after hitting the activation push button on the device to activate the power from a rechargeable inside battery. The blade, composed of silver, gold, platinum, and ceramic coating, to heat a rolled cast leaf sheet of actual tobacco saturated with glycerin creates an aerosol from heating, not combustion [65].

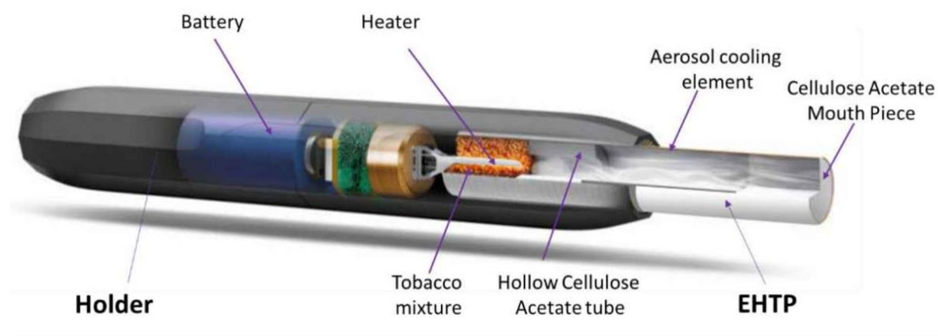


Figure 8. IQOS anatomy from PIM's report [66].

When you briefly press the heating button, the device will vibrate, and the indicator light will flash until it reaches the operating temperature. The device can be used once the green light is steady. The duration is roughly six minutes, or fourteen puffs, whichever comes first. The device will vibrate after 30 seconds of pushing or two shots. The light will become orange, and the product will shut off automatically [67].

1.5.3 The Debate about HTP Reduced Risk

Philip Morris is pursuing the concept of reduced risk to consumers. While government agencies demand more research, other researchers' studies are concerned about it.

Philip Morris International Products, knowing that millions of smokers seek less harmful alternatives to combustible cigarettes, has developed and acquired technologies to provide smoke-free nicotine delivery products [68]. One of these products is the IQOS 2.4 plus, a heat-not-burn product and the focus of this thesis. Because of the lower temperatures using about 600°F in heated tobacco products(HTP), which is in IQOS heating at temperatures below 350°C (350 degrees Celsius) less than 900°F (the temperature needed in combustible cigarettes), and the lack of combustion produced by these products, tobacco manufacturers claim that heat-not-burn products are healthier than traditional cigarettes [69]. Compared to ordinary cigarettes, this unique heat-not-burn tobacco product emits much fewer quantities of tar, carbonyls, VOCs, CO, free radicals, or nitrosamines, which may reduce health risks for smokers [70]. This aerosolization process is proposed to reduce the user's exposure to toxic and unsafe chemicals from tobacco combustion. Thus, the consumer gets the 'harm reduction' component of EC, and a conventional cigarette's mouth/throat feel [65].

Farzad 2018 [26] reviewed PM's MRTP application to assess the toxic effects reported by PM for their animal and human studies. Farzad 2018 said there is little evidence that HTPs are less dangerous than traditional cigarettes “because the IQOS-exposed mice in PM studies showed evidence of pulmonary inflammation and immunomodulation. The human users show no evidence of improvement in pulmonary inflammation or function in smokers who were switched to IQOS.”

Chen-Sankey 2023 [71] expressed concerns that modified risk tobacco product (MRTP) statements for heated tobacco products (HTPs), implying lower exposure than conventional cigarettes, may encourage product initiation and transition among young people [71].

National Instate of Health (NIH) stated that the effects of a hypothetical MRTP claim for HTPs on young adults' intention and perceptions of using HTPs were examined, and whether these effects differed depending on their current cigarette and e-cigarette use [71]. According to the NIH, there is no evidence that these products are less dangerous than regular cigarettes. Indeed, more than 20 hazardous compounds have been found in higher concentrations in heat-not-burn products than in typical cigarette smoke; exposure to toxic chemicals is also higher when compared to e-cigarettes. There is some evidence that new chemicals exist in heat-not-burn products that are not found in ordinary cigarettes and that these chemicals may be poisonous and hazardous [72].

The Food and Drug Administration (FDA) demands more computational toxicology studies with details of the chemical analysis, such as the quantitative structure-activity relationship (QSAR) and structure-activity-relationship (SAR) and QSAR models to characterize the potential impact [73]. Heat stick aerosols require a sufficient computational toxicological assessment to estimate possible harmful effects in users before toxicity becomes apparent [73]According to the FDA, Philip Morris Products applications showed that switching from combustible cigarettes to the IQOS system would reduce exposure to potentially harmful chemicals. Some substances were higher in the heat stick aerosol than in the smoke of the combusted cigarette.

The FDA demands that more research be conducted to better understand the potential impact of the exposure of the Heat Stick aerosol. The FDA expressed that the application lacked details on the quantitative structure-activity relationship (QSAR). The FDA requires more information on how Philip Morris Products interpreted that the heat stick aerosol would have fewer adverse effects on users than combusted cigarette smoke [73]. The FDA has two application requirements. First, the "Modified Risk Tobacco Product" (MRTP) application is a demand to make health claims regarding IQOS, and the second is the "Premarket Tobacco Product Application" (PMTA) application, which is an application to market IQOS in the United States. Despite the claims that switching from combusted cigarettes to the IQOS system would enormously minimize inhaling dangerous or possibly hazardous chemicals, several compounds were higher in Heat stick aerosol than in combusted cigarette smoke [73]. Although the study showed that switching from combustible cigarettes to the IQOS would significantly reduce exposure to harmful or possibly hazardous chemicals, some chemicals in Heat stick aerosol were higher than in combustible cigarette smoke [73]. Additional research on these exposures is needed to characterize the potential impacts [73].

1.5.4 How to Purchase Different Products

According to a U.S. International Trade Commission ruling, Philip Morris International's IQOS heated tobacco device infringes two patents owned by rival British American tobacco. As a result, it is prohibited from being imported or sold in the US [74]. Yet, there is a significant online presence, including numerous websites. The product used in this thesis is the IQOS 2.4 Plus, shown in **Figure 9**, online (no consumables/no heat sticks) for around US$ 105 [75]. However, this website offers payment options for PayPal and Bitcoin. When attempting to purchase with PayPal, we get an error: "Since buying or selling tobacco products or e-cigarettes online with PayPal is prohibited (SECTION 15), we only accept personal payments to avoid fees and possible taxes" [75].

It is unclear whether we can obtain IQOS in the US anymore. At this point, we purchased one IQOS 2.4 plus device. We ordered the IQOS and the Heat sticks on May 8th, 2019. We had ordered the IQOS from Amazon and the heat sticks from Myheatstore.com, but the Myheatstore.com website is no longer available.

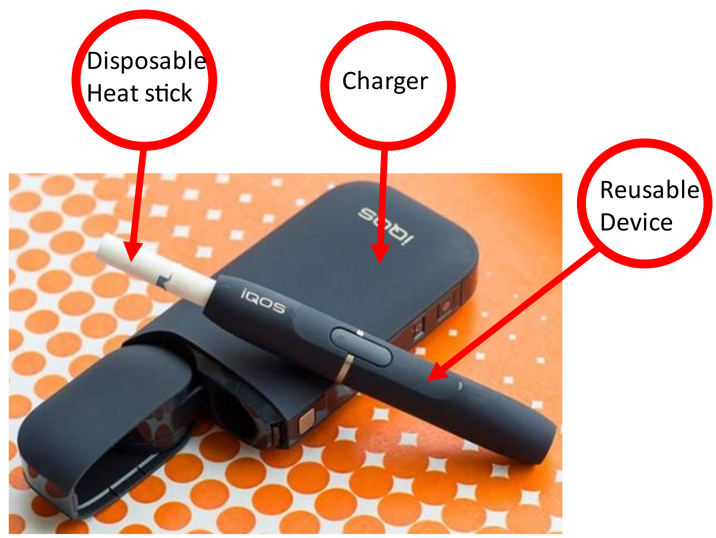


Figure 9. IQOS components from the Truth Initiative website [76].

Philip Morris updates its designs nearly every year, and each design is unique in design and manufacturability. This is a website for the wholesaler-to-distributor [76].

1. After we decided on this version of IQOS 2.4 (number 1 in **Figure 10**) to begin our research, Philp Minorities released its new design for the market.

2. IQOS 3 DUO (Number 2 in **Figure 10**) This model may be used twice without requiring recharging in between. The charger is faster, and the design is smaller and thinner than the prior design. The device only weighs about 99 grams. The charger opens by a magnetic side door.

3. Lil SOLID (number 3 in **Figure 10**) This model may be used three times without a break and without being recharged in between. One charge can be enough for 25 sticks.

4. Lil HYBRID (number 4 in **Figure 10**) This model uses an unusual design of MiiX heat sticks and pods. The device has a rich taste or can create a new flavor as it simultaneously heats the heat stick and pod. The pod and the heat stick must be interred into the design, and the device turns on once the heat stick hits the heater. The device has a screen that can count the puffs.

5. 7IQOS VEEV (Number 5 in **Figure 10**) This device does not use sticks but disposable pods. Like the electronic cigarette, this device has a grid that must be wholly immersed in the liquid, so every puff has a rich taste. This device has a controllable funny vibrate. The battery in this version lasts about 30 minutes and is super-fast recharging.

Figure 10. IQOS versions from a sample distributor [77].

1.5.5 Variety of Heat Sticks Available and What They Look Like

IQOS relies on actual tobacco. The manufacturer designs tobacco sticks to be used only for their IQOS, known as "Marlboro Heat Sticks" or "HEETS". Both HEETS and Marlboro Heat Sticks are produced by Philip Morris International (PMI). HEETS and Marlboro Heat Sticks contain ten packs of 20 sticks, each carton costing around $54 - $ 66. One package of twenty Marlboro Heat Sticks is in the price range of US$ $4-$6 [77]. The available variety of heat sticks varies by containing different flavors and nicotine strengths. Heat sticks are frequently available in various nicotine strengths to meet varied levels of nicotine dependence or preference. These varieties may be referred to as "regular", "strong," "mild," or similar terms. Shape and size, flavors, and packing are the most popular features of heat sticks for heated tobacco products. Many heat sticks are typically packed in compact packs or sleeves. Packaging design can also differ depending on region and brand. Some manufacturers apply color coding on the packaging of heat sticks to differentiate between flavors or nicotine concentrations and usage instructions. Heat sticks are usually the same diameter as ordinary cigarettes. Heat sticks offer different flavors, including menthol, tobacco, and berry. Specific flavors' availability may vary depending on local laws. Based on our measurements, the length of the heat stick is 45 mm, shorter than standard cigarettes, which average 85 mm.

Figure 11. The heat stick's brands and size. The picture to the left shows the Heat stick size vs. cigarettes, while the other two photos show the brands of the heat sticks.

1.6 THE FAMILY OF WPUM™ MONITORS

The RTL research group designed their topography monitor used in several field studies. The topography monitor development at RTL has undergone several revisions, including sensor mechanisms, electronics, and battery capabilities. Monitor designs have changed to handle new electrons, evolving technologies, and external appearances for different companies.

Over the years, the market for inhaled tobacco products has gone through significant changes and developments. Various factors drive these changes, including shifting consumer tastes, health concerns, and regulatory efforts to decrease the harm associated with traditional combustible cigarettes. We consider form modifications because we require a monitor to accommodate every varied design, and it is challenging to build a single monitor that operates with multiple electronic cigarettes. Design and fabrication are made possible by considering form factors and using scenarios in product development. This allows for designing and producing product-specific topographical monitors adaptable to emerging alternative tobacco products, becoming less invasive and more agreeable to research participants. For example, the monitor design for the IQOS should have a circular mouthpiece to mimic the heat stick that smokers used to feel. It is smooth and round from the top, giving the smoker the feeling that the monitor is absent. Because the inhaled tobacco product market is rapidly changing, designing the proper monitor for regulatory changes is critical to making informed decisions about tobacco use and harm reduction strategies.

Given the ever-changing landscape of inhaled tobacco products and the emergence of devices like IQOS, there is an increasing need for monitoring and research to assess their influence on public health. This involves comparing these products' safety, efficacy, and long-term health implications to regular cigarettes [78]. This data would be critical for policymakers, public health professionals, and consumers to make educated judgments regarding the usage of these goods and to set appropriate rules and guidelines [78]This thesis aims to design a tool to monitor IQOS puffing behavior in the natural environment. The wPUM IQOS monitor will provide data that can be used in the PES and BAES to emulate user behavior for IQOS, generate realistic emissions IQOS, and input lung deposition models. The wPUM IQOS monitor will also provide the data needed to assess behavior patterns and the overall consumption of IQOS users.

The orifice dimensions and pressure sensor seating dimensions for the pressure sensor board were fixed. These dimensions were the same as those of Cigarette Gen three and the Juul monitor, which was proven and tested to give good sealing in previous work for combustible cigarettes. The cigarette flow path was used since we do not have topography data for IQOS. **Figure 12** shows the initial starting point for the IQOS monitor design.

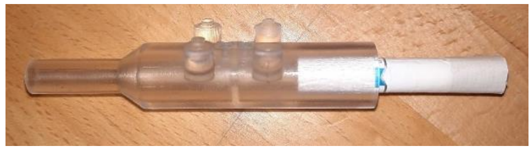


Figure 12. The initial design of the mouthpiece. This part was the core of our monitor, as it was validated and tested in a previous study.

1.6.1 wPUM Electronics Generations

In this section, we will compare five different types of monitors produced by RTL. While this research focuses on the geometrics and characteristics of the monitor, this section will also include a comparison of several other properties, such as the electrics sensor and storage. **Table 1** shows pictures of the internal components of these five monitors while **Table 2** is showing detailed comparisons of the essential properties. It is observed that the design of the earlier monitor is more straightforward, using a microcontroller-based development kit as a base for their electronics. In contrast, later designs use a more sophisticated microcontroller with a custom design system and PCB. Two main types of pressure sensors are used in those five monitors. In the first three monitors, the prototype Gen1 and Gen2 used the Honeywell pressure sensor, while in later designs, Gen2, Gen3, and Gen 3 (A), the Sensirion SDP3x Differential in a size of ±150 Pa or ±500 Pa is used. In addition, enhancements have been made to the power capabilities of these monitors; the earlier design used Tadiran Lithium Battery Size 2/3 AA, 3.6 Volt 2 Batteries connected in series, and later designs like Gen 3 (A) use LiPo Rechargeable batteries, 150mAh and up to 1200mAh. Adding the recharging capability would make it convenient for the users to connect the device to an electrical source, like how they recharge their phones, instead of asking them to bring the monitor back to the lab to replace the batteries. This study's designed and tested monitor is considered part of the Gen 3 monitors as it uses the same basic internal electronics, pressure sensor, and batteries as the already produced Gen 3 monitors for Juul, compatible cigarettes, and hookah. The IQOS monitor, designed for this thesis, will use Gen 3 (A+) electronics.

Table 1. Pictures of electronics used in all wPUM monitors produced at the RTL (the front and back side of each electronic board).

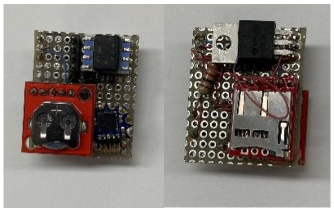
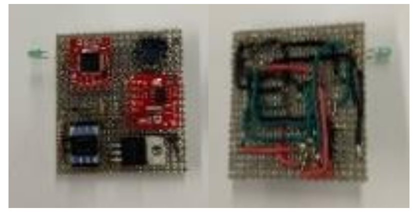
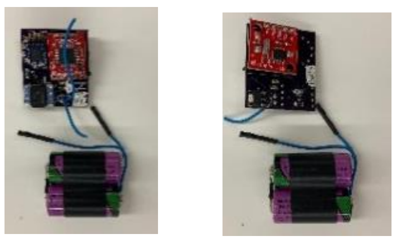
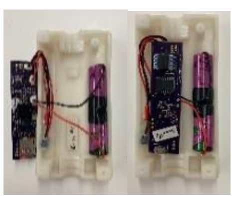
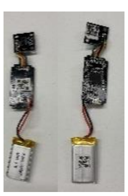
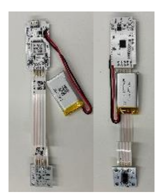
Generation	**Revision**	
Prototype	#1	#2
		
Gen 1		
Gen 2	Long Version	Short Version
		
Gen 3	A	A+
		

Table 2. The evolution of the first, second, and third-generation electronic features used in the wPUM family of topographical monitors.

wPUM™ Monitor Electronics	Prototype	Gen 1	Gen 2	Gen 3 (A)	Gen 3 (A+)
Microprocessor (the CPU)	Atmel Atmega328P (mounted on Tinylily board)	Atmel Atmega328P (mounted on Tinylily board)	Atmel Atmega328P	STM32F401RE ARM MCU	STM32F401RE ARM MCU
Data Storage	Micro SD Card	Micro SD Card	Micro SD Card	On board flash W25Q128JV NOR Flash	On board flash W25Q128JV NOR Flash
Pressure Sensor Manufacturer and Model Number (size in Pa)	Honeywell HSCDRRN002NDAA5 ± 2" WC (498Pa)	Honeywell HSCDRRN002NDAA5 ± 2" WC (498Pa)	Honeywell HSCDRRN002NDAA3 ± 2" WC (498Pa)	Sensirion SDP3x Differential ±150 Pa or ±500 Pa	Sensirion SDP3x Differential ±150 Pa or ±500 Pa
Battery	Primary Cell Tadiran Lithium Battery Size 2/3 AA, 3.6 Volt 2 Batteries in series	Primary Cell Tadiran Lithium Battery Size 2/3 AA, 3.6 Volt 2 Batteries in series	Primary Cell Tadiran Lithium Battery Size 2/3 AA, 3.6 Volt 2 Batteries in series	Compatible with LiPo Rechargeable 150mAh,350mAh	Compatible with LiPo Rechargeable 150mAh,350mAh, and 1200mAh
Pressure Sensor Connection to Core Board	Four wires	Four wires	Four wires	Four wires	ribbon cable
Data Access	External SD Card Reader	External SD Card Reader	External SD Card Reader	USB Serial Port	USB Serial Port

Pressure Sensor Connection to Orifice Plate	1/16" ID Tygon Tubing	1/16" ID Tygon Tubing	1/16" ID Tygon Tubing	Direct O-Ring mount to orifice plate openings	Direct O-Ring mount to orifice plate openings
Puff Recording Mode	Continuous recording when switched on	Continuous recording when switched on	Continuous recording when switched on	Puff Activated: wake up at the beginning of a puff and start recording.	Puff Activated: wake up at the beginning of a puff and start recording.

Figure 13 shows the whole assembly of the electronic elements of Gen 3 (A+) wPUM, which is used in the IQOS monitor in this work.

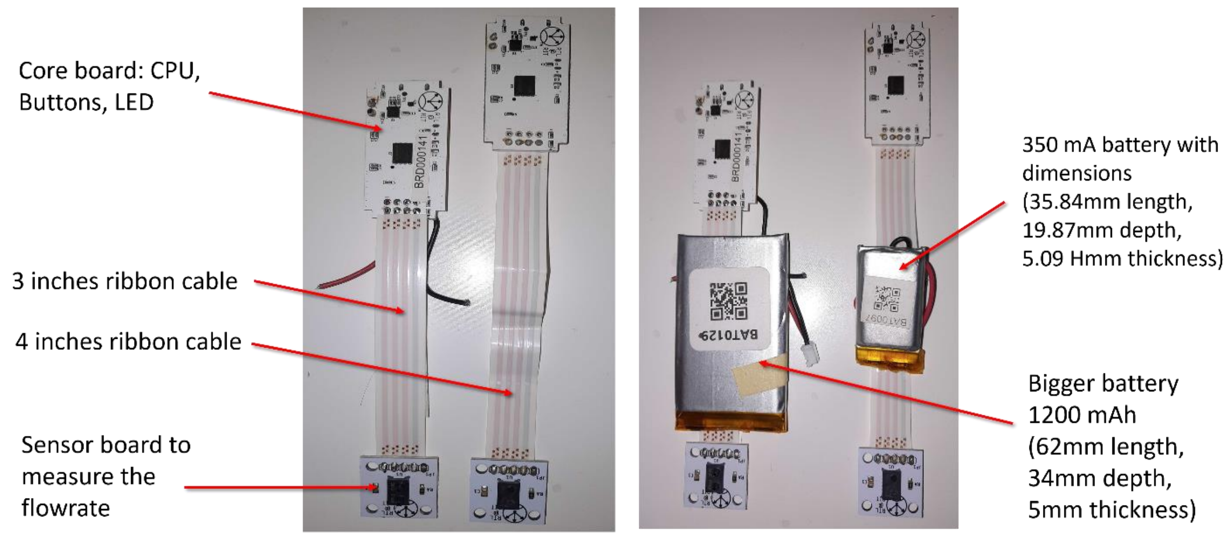


Figure 13. Gen 3 (A+) wPUM electronic parts.

1.6.2 wPUM Form Factors

The external geometry of the monitors accommodates the type of tobacco product. Monitor designs evolved for different products to accommodate new electronics, emerging products, and exterior shapes. **Table 3** Shows the monitors and their revision for each generation.

Table 3. Displays the monitors along with each generation's modification.

Electronics Generation Number	**Electronics Revision**	**Form Factor for the Casing**	**Figure Number**
1	----	Cigarette	10
		Cig-a-like	10
2	Short Style	Cigarette	11
	Long Style	Pen style	12
		Hookah	13
3	(A)	Cigarette	14
		Hookah	15
	(A+)	JUUL	16
		puff bar	17
		Hyde-original	18
		Ace	19

1.6.2.1 Form factors using Gen 1

Gen 1: Cigarette and Cig-a-like

The primary wPUM monitor was designed for a cigarette with comfortable finger grips to support how cigarettes typically fit in normal usage **Figure 14.** This monitor was modified to take the various diameters of Cig-a-Like electronic cigarettes by installing the proper adapter.

Figure 14. The cigarette monitors used Gen 1 electronics.

1.6.2.2 Form factors in Gen 2

Gen 2 Short Style: Cigarette

Gen 2 Long Style: Pen style and Hookah

Two form factors are produced for Gen 2 monitors: short and long. The two versions are designed to minimize interference with the user behavior of the specific tobacco product. The short version is dedicated to combustible cigarette products known for their small size and exact hold position by the users. Users usually hold these two products between their index and middle fingers. To provide the possibility of keeping the monitor in this position, the Gen 2 short version is designed with two notches on the sides like Gen 1, as demonstrated **Figure 15** The size of the electronics was a significant design restriction. Since the creation of this monitor, smaller, more discrete monitors have been made possible by reducing the size of the necessary electronics.

The long version of Gen 2 is used for pen style and hookah. These two products are inherently bigger than combustible cigarettes and require different handling and mouthpiece requirements**. Figure 16** Demonstrates the long version of Gen 2 monitors used for pen style while **Figure 17** displaying the long version of Gen 2 monitors used for hookah.

Figure 15. Gen 2 short-style electronics are used for cigarette monitors.

Figure 16. The pen-style monitor used Gen 2 long-version electronics.

Figure 17. The long version of Gen 2 monitors is used for hookah.

1.6.2.3 Form factors using Gen 3 (A) and Gen 3 (A+)

Gen 3 (A): Cigarette and Hookah

Gen 3 (A+): Cigarette, Hookah, JUUL, Puff Bar, Hyde-Original, and Ace

From this generation, we switched the connection between the orifice plate and the sensor board from flexible tubes to the direct O-ring; this feature helped us to make the design smaller. Therefore, the form factor for the **cigarette** monitor to use the new electronics ultimately made the monitor fit in a pocket **Figure 18.**

The **Hookah monitor Figure 19.** has all the electronics inside, the most significant change from the previous version of the Gen 2 wPUM hookah monitor. This does away with the need for the tabletop box and replicates the design of a hookah hose and mouthpiece sold commercially. The monitor is ergonomically made to comfortably handle in the palm like a hookah hose purchased commercially. The monitor's distal end was designed with a barb to accommodate a disposable hookah hose. The monitor has two constituent parts: the body and the lid.

The new electronics led to the development of the monitor's pod-style e-cigs. The lab first developed **the JUUL monitor Figure 20**. The user loads the product into the JUUL monitor while a piece of rubber plug keeps it from falling out. The electronics inside the container are held safely by a sliding mechanism. This monitor has a mouthpiece that matches the device to suit the natural form factor of the mouthpiece for users. The monitor was changed to accommodate the **puff bar Figure 21, Hyde-original Figure 22, and Ace Figure 23.** Every monitor is identical to the original device regarding the housing and the insert shape **Figure 24**. The difference between them is the dimension of the channel that holds the e-cig size, as shown in **Figure 25.**

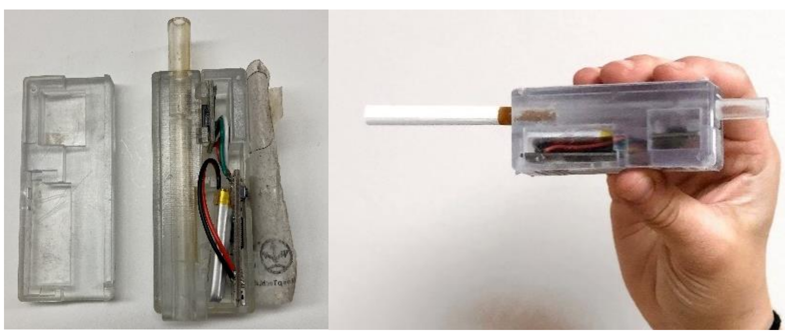


Figure 18. Gen 3 electronics are used for combustible cigarette monitors. The left side shows internal assembly while the right side shows the monitors in the use case scenario with the actual cigarette inserted.

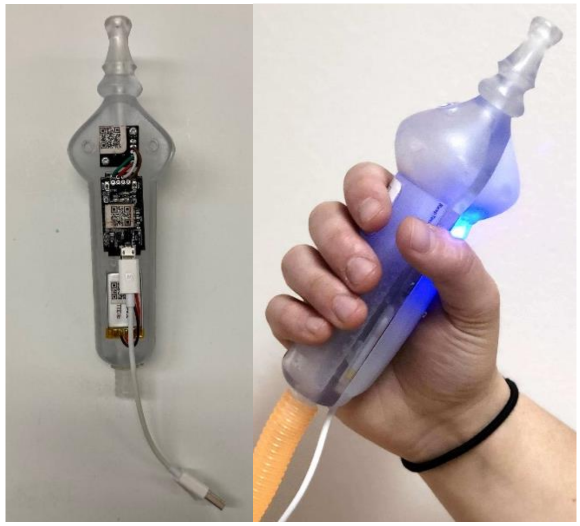


Figure 19The Hookah monitor used Gen 3 (A) and (A+). The left side shows the internal electronics, while the right side shows the monitor connected to an actual hookah hose held by a user.

Figure 20. The JUUL monitor used Gen 3 (A+). The see-through material on the right side shows the internal electronics, while the left side shows the monitor held by a user.

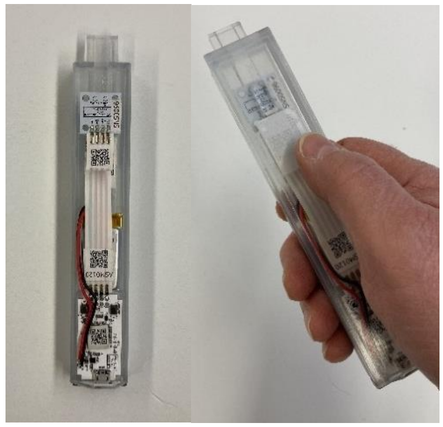


Figure 21. The Puff Bar monitor used the Gen 3 (A+) electronics assembly as shown on the left side while the right side shows the monitor in use.

Figure 22. Hyde original monitor used Gen 3 (A+) electronics as seen on the left side and the monitor in use on the right side.

Figure 23. Ace monitor with the electronics Gen 3 (A+) inside and the handheld.

Figure 24. Displays, from left to right, Gen 3 (A+) monitors form for Hyde-original, JUUL, and Puff bar.

Figure 25. Displays, from left to right, Gen 3 (A+) monitors' insert form for Hyde-original, JUUL, and Puff bar.

2 The Design Process

This chapter describes the design process that was applied in this work. **Figure 26** shows the complete design process described in this chapter. Each step in this figure is described in detail in the rest of this chapter.

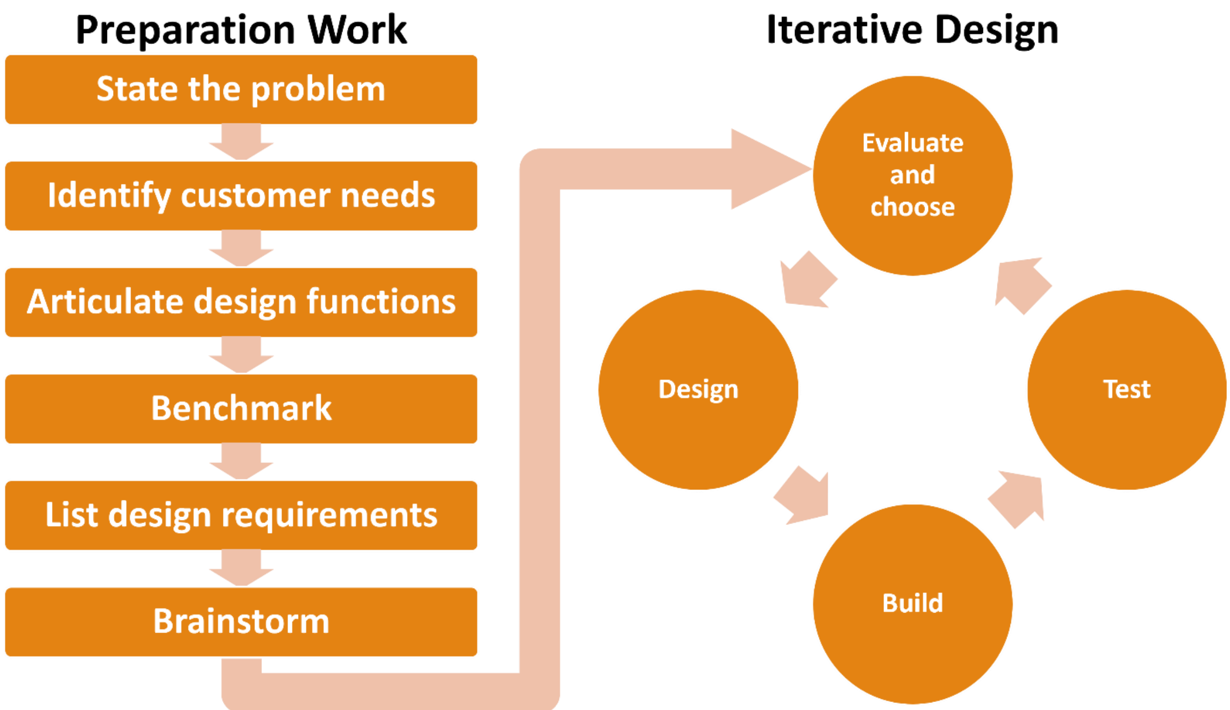


Figure 26. This work follows the complete design process.

2.1 State the Problem

A problem statement is a short description of a specific problem that needs to be solved. Our problem is represented by designing a topography monitor for IQOS Heat Not Burn Tobacco Product using the 3rd generation wPUM electronics.

2.2 Identify Customer Needs

A customer's need is figuring out what and how a customer wants a product to perform. The non-technical process of identifying customer needs is strongly linked to design specifications. The needs have been established before the design process. These requirements guide the design process decision-making.

2.3 ARTICULATE DESIGN FUNCTIONS

A design's purpose is to fulfill a purpose and explain why and where it is needed. Iteration becomes necessary when a method is applied and fails to achieve its goals. By creating the product's physical form, the design function assumes the lead in determining how to best meet customer needs. Additionally, the design function generates information on a wide range of additional product-related subjects before, during, and after the product's end of life.

2.4 BENCHMARK

Benchmark means something that acts as a standard for others to be evaluated or examined. This represents all the experiments, measurements, and tests the specialists have done to guide the decision. Benchmarks include operating parameters, accuracy, size, and all the process patterns.

A benchmark is a standard by which other devices are evaluated or examined. This is a combination of every test, evaluation, and assessment the team conducted to make the choice. Operating parameters, precision, size, and every pattern in the process are all benchmarks.

2.5 LIST DESIGN REQUIREMENTS

A comprehensive list of criteria outlines every aspect of the design. Functional characteristics known as design requirements aid in selecting the most promising concepts and design elements. We will choose whether to develop a new sub-design or use an existing one for every design function. Based on feedback from stakeholders, explicit and quantitative design requirements will be created for each new sub-design.

2.6 BRAINSTORM

Brainstorming is immediately coming up with many ideas for a project before giving some of them further thought. Brainstorming will be done for this thesis to select the design functions required for a new sub-design concept.

2.7 Evaluate and Choose

Evaluating something means determining its worth, significance, quantity, or quality. To determine the final design, every idea will be reviewed concerning the design requirements, with appropriate weighting factors used. Stakeholder input will also be taken into consideration.

2.8 Design, Build, Test, Iterate

Formal CAD model design can start after the first design concept is selected. The design considers how each component works separately and as a whole system or assembly. To determine how each part works on its own and how it interacts with the other parts, each component should be tested separately and as an assembled whole.

This project implements two types of building processes. The first type uses lower-end 3D printers and materials during the iterative design process, while the second type prints the final product using higher-quality printers and materials. The build process includes 3D printing of the designed monitors and all associated post-processing, such as cleaning the printed pieces.

Testing is an inherently important part of the iterative design and build process. The product's dimensions and the fitting of various parts are continuously validated as the design progresses.

Some of the essential dimensions tested in the iterative design include the connection between the heat stick and the monitor, the housing of the IQOS in the monitor, the housing fit of the pressure sensors and O-rings, and several other parts discussed later in the document.

3 METHODS FOR APPLYING THE DESIGN PROCESS

3.1 STATE THE PROBLEM

There is a need to measure topography in the natural environment using the IQOS heat-not-burn tobacco product. It is necessary to observe the typical behavior of people who use a specific kind of electronic cigarette, IQOS, by developing and testing a device that could hold this product. This work helps the FDA as there are currently no widely used testing guidelines to assess their influence on health [79].

This study designs a wPUM monitor structure for IQOS devices. The monitor consists of several components, including a holder for the IQOS, the orifice for flow rate measurement, the mouthpiece, and the electronics housing with the lid to keep the electronics safe.

3.2 IDENTIFY THE CUSTOMER NEEDS

The first step in any design project is understanding the final product and the expected outcomes or features based on customer needs. In this work, the customers included the IQOS users participating in the study, the technician who handled the monitor, and all research teams involved. Understanding the needs and expectations of all these customers required an intensive literature review of similar monitors, an understanding of the IQOS device and its operation, and an in-person discussion with the research group personnel. Based on this restricted exploration, the following requirements are defined.

The requirements can be divided into two main categories: general requirements for any wPUM monitors regardless of the targeted tobacco product and IQOS-specific requirements. The general requirements define the outer shape and functionality of the monitor. This list of general requirements was obtained from the literature [48], [80] and discussion with RTL lab members, which concluded the following list:

- Outer shape
    - Lightweight.
    - Minimal distribution to actual user behavior.
    - Rugged
    - Safe

- Reusable
- Aesthetic
- **Complexity**: Easy to use
  - I. Easy to clean
  - II. Low-complex
  - III. Small
  - IV. Smooth
  - V. Consider IQOS shape and size
  - VI. Ergonomic for technician and user
- Functionality
  - Wireless
  - Port for USB for recharge and data transfer
  - Fit the electronics assembly.
  - Supports a battery size of 1200 mAh and a variable for variable battery size.
  - Repeatable seal between HTP and the wPUM monitor.
  - Use a pressure pad to ensure a force pushes the pressure sensor board into the taps.

The IQOS-specific requirements are concluded based on an in-depth analysis of the operation of the IQOS monitor, as already discussed in **Introduction 1**1 and the previous natural environment studies conducted in the RTL [48], [80].

- IQOS-specific requirements
  - Expose the IQOS activation button, making it easy to hit.
  - Provides air inlet for IQOS.
  - Hold the IQOS and keep it from falling while giving a good seal.
  - Provides support to the tobacco stick.

3.3 Define Design Functions

This section defines generalizable design functions that can be applied to the wPUM monitor family. All wPUM monitors designed by the RTL included these six design functions, as shown in **Figure 27**. Below are the names and design functions for each sub-design of a topography monitor:

1. **Mouthpiece attachment**
    a. Mouthpiece—The mouthpiece design channels the flow from the orifice chamber to the user's mouth, allowing for a comfortable and safe interface.
    b. Orifice chamber—The function of the orifice chamber is to channel the aerosol flow from the inlet of the orifice chamber to an orifice plate inside the room, across the orifice plate, where the flow experiences a pressure drop, communicate the pressure drop to the pressure taps, and finally channel the flow to the exit of the orifice chamber.
    c. Pressure sensor seating—The pressure sensor seating design supports the sensor and creates a seal between the barbs and the pressure taps in the orifice chamber.
2. **Product attachment**
    a. Interface—The function of this part is to create a seal between the tobacco product and the monitor and channel the aerosol from the product to the orifice chamber (the pink cone in **Figure 27**).
    b. Holder—The product attachment design supports the physical connection between the monitor and the tobacco product (the brown part in **Figure 27**).
3. **The Electronics Housing**
    a. Electronics chamber—The electronics housing design holds the electronics assembly in place (including keeping the pressure sensor from becoming disconnected from the monitor) while providing access for routine maintenance. The housing includes the chamber, lid, and lid-locking designs.
    b. The lid locking—The lid mechanism was used for the IQOS monitor. The lid protects the electronics assembly and has a pressure pad that applies proper pressure on the sensor board to give a good seal between the taps and the orifice chamber.
4. **Electronics assembly—**The function of the electronics assembly design is to connect the battery, the pressure sensor chip, the MicroController Unit (MCU), and other functions such as data storage, battery charging, and computer interface. The realization of the Electronics Assembly may vary between 2 and N subassemblies or/and components. The Gen 3(A+) electronics assembly consists of two components (the battery and ribbon cable) and two subassemblies (the pressure sensor board and the core board), as shown in **Figure 28**.

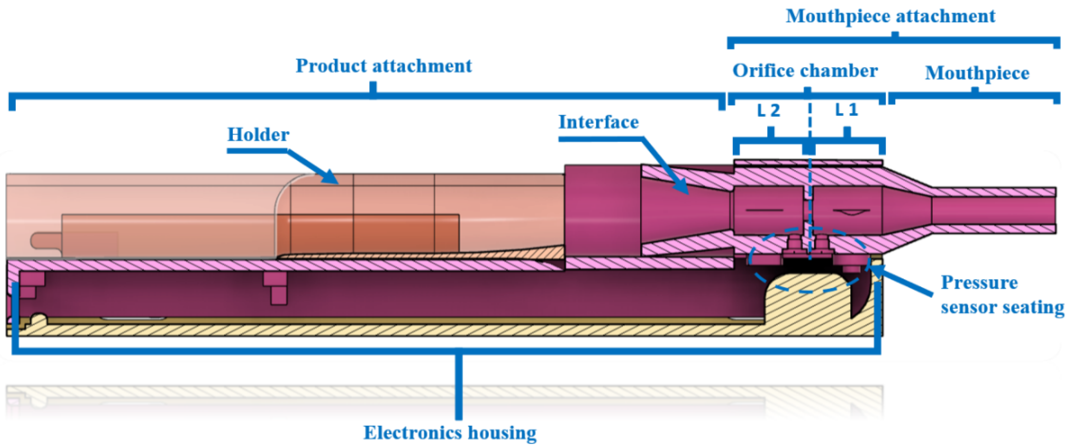


Figure 27. The diagram generalizes the six common parts of all the wPUM monitors.

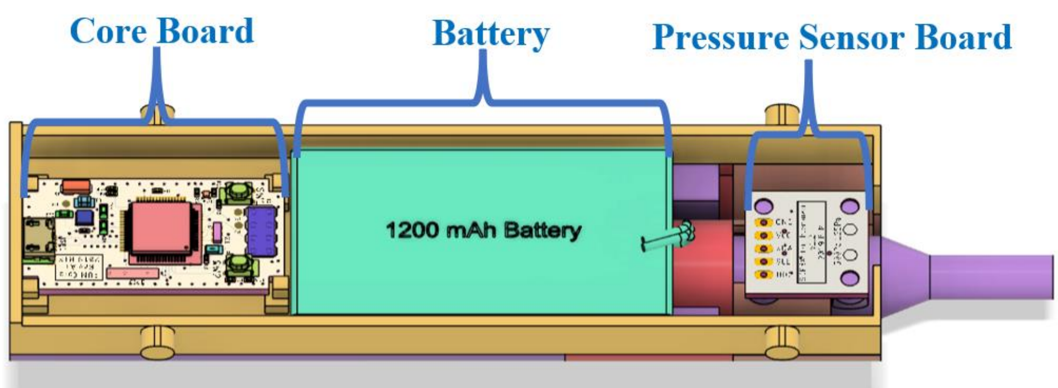


Figure 28. The electronics housing contains the electronics assembly Gen 3 (A) the IQOS monitor uses.

3.4 Design

The monitor design will be completed using Autodesk Fusion 360 software, which has various capabilities required for a smooth transition from design to manufacturing. An attractive feature of this software is parametric design, which allows the flexibility to change design dimensions smoothly. This feature is needed explicitly in the iterative design process followed in this work, which includes changing sizes based on repetitive building and validation.

In parametric design, all or most dimensions are abstracted in a table and defined as variables with meaningful and callable names. Variables can also be described as functions of other variables in a programable function. For instance, a variable X can be the length of a particular part in the design. The second variable, Y, can be defined as a function of X, e.g., Y=X+2.

The importance of the parametric design feature of Autodesk Fusion 360 is explained in the following example.

1. Carefully check each measurement in the actual design to improve the perspective and aid in the fusion of the design.

2. I utilized the parameter tool in Fusion 360. This function lets us quickly change any dimension by accessing the table and modifying the number within. The software system can also store and keep a table containing the measurements. While entering the dimensions, each parameter's name, value, and description must be entered into the database. The saved parameters can be directly inserted into the equations to start the design.

3. Using what I referred to as the origin position, I made the X-, Y-, and Z-axis designs.

4. Several sketches can be made for each plan. For smooth calls, each plane must have a specific name.

5. The parameters previously input in the table in point 2 can be called.

6. Once the drawing is completed, the commands in Fusion, such as extrude and fill or fillet, will be simple to utilize. It would also be helpful to save those dimensions in the parameter table.

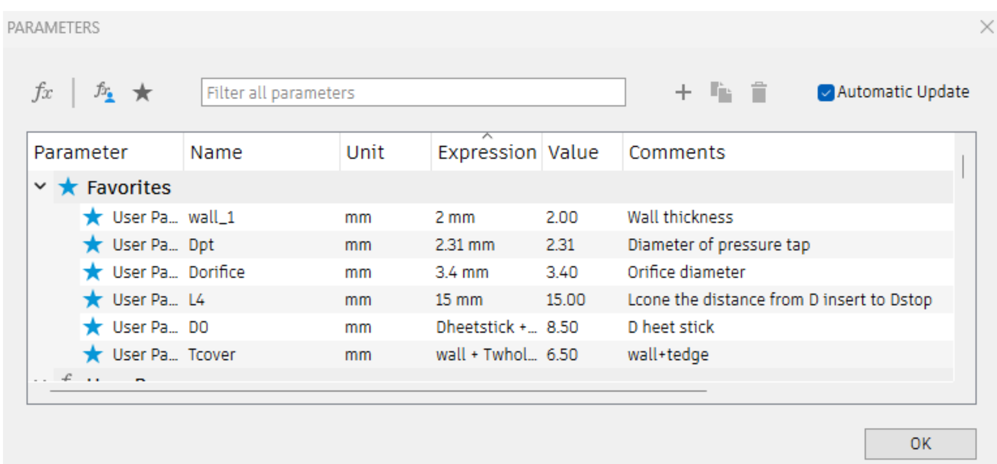


Figure 29. The parameters tool in Fusion 360.

3.5 Build

The Fab Lab is a model fabrication facility on the RIT campus at Booth Hall, A620. It is part of the College of Art and Design. It utilizes 3D printers, laser cutters, CNC routing machines, and other modeling technologies. Students, staff, and faculty use it at RIT. The Fab Lab produces 3D printing of iterative designs in this research using fused deposition modeling (FDM), stereolithography (SLA), and polylactic acid (PLA) printers. When conducting this research, the Fab Lab used a Jira-based website to submit projects. Recently, the Fab Lab switched to using another website, making the Jira-based process obsolete. The official facility website (https://www.rit.edu/facilities/fab-lab) details the available services and the project submission process. We chose to use FabLab because it is affordable for prototypes requiring a fast turnaround without waiting a long time. It is handy and faster for goods because it is located on campus. Fab Lab charged us $3 to $50 per piece, depending on the material and size.

For the final design, we printed many prototypes at TriMech https://trimech.com/, which offers more accuracy and a more comprehensive range of material options. The type of plastic specifically designed for medical equipment manufacturing is known as medical-grade plastic. Therefore, we will look at various materials until we find one that will work for us. We decided to employ medical-grade plastics called Somos11122XC since we needed our monitor to be safe for the users when it touches their mouths [81]. TriMech charged us $100 - $200 per piece, depending on the material, quality, and number of orders.

4 IQOS wPUM Monitor Design

This chapter is divided into three sections, each detailing the design process of one of the three main parts of the IQOS wPUM monitor: mouthpiece attachment, product attachment, and electronic housing. The design process starts with stating the requirements and customer needs for the part, which are used as the basis for the rest of the work.

4.1 Mouthpiece Attachment Design

Attachment is the interface or connection between the monitor's mouthpiece and the tobacco product (Heat stick). Initially, the RTL developed a monitor to achieve a maximum resemblance to the sample IQOS. The mouthpiece in the IQOS is identical to the heat stick’s dimensions. Regarding functionality and usage, wPUM topography monitors comply with regulations for inhaled tobacco products. The mouthpiece has three parts, as shown in **Figure 30**: The orange part is called the “Mouthpiece,” the green cylindrical part is the “Orifice Chamber,” and the blue part is called the “Pressure Sensor Seating.”

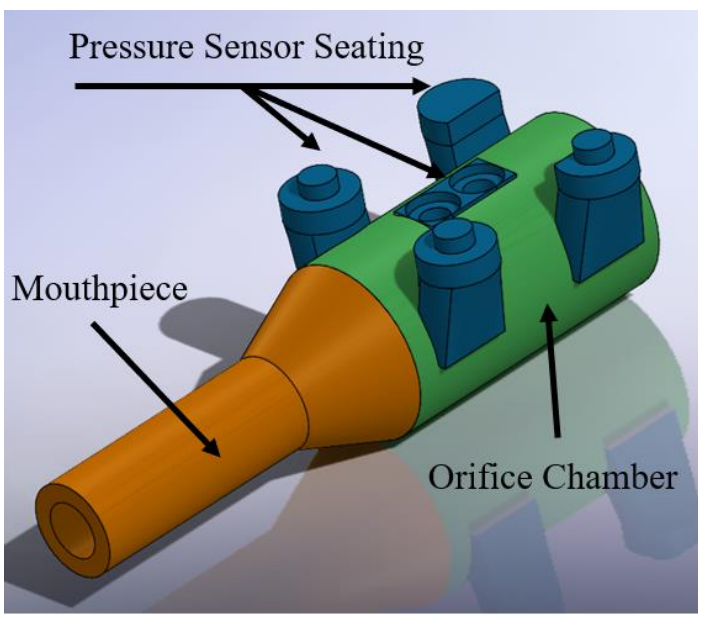


Figure 30. Illustration of the sub-design parts of the “Mouthpiece attachment”.

4.1.1 Requirements

The design requirements for the mouthpiece attachment design are:

1. Mimic the heat stick in shape.
2. Does not affect the airflow.
3. Has a strong wall around the inner channel.
4. Must prevent leaking between the heat stick and the monitor
5. Minimize the total dead spaces inside the flow chamber.

4.1.2 Design

The first step is to have total geometrical measurements and analysis of the device itself (IQOS); this will include the heat stick length and diameter as well as the whole device length and other geometrical characteristics of the device itself. These measurements will guide the design decisions in the wPUM monitor casing. The specific measures of the IQOS include the length of the device without the heat stick, the length of the device with the heat stick inserted in its place, the length of the heat stick by itself, and the diameter of the heat stick at the filter side. This monitor's two critical dimensions were the battery's width and the main board seating.

4.1.2.1 Mouthpiece

The Proximal end of the monitor -called the mouthpiece- touches the user's mouth, as shown in **Table 4** and **Figure 31**. The length of this component is represented by **(L 0 (L mouthpiece)**). The cone shape attached to the tube gives a smooth flow rate and prevents sudden changes in the cross-section of the particle flow path. The outer diameter of the mouthpiece (**D 0 (outer))** replicates the heat stick. The inner diameter of the mouthpiece is called (**D 0 (inner)**). This diameter is less than that of the cigarette Gen 3, which was 8 mm. Based on my experiment, the heat stick's diameter (**D 0 (inner**) is about 7.5 mm.

Table 4. A summary of the mouthpiece dimensions used in the IQOS monitor produced in this work.

Feature	**IQOS**	**Cigarette Gen 3**
D 0 (outer)	7.5 = D Heet	8 = D cigarette
D 0 (inner)	3.4	4.57
L0 (L mouthpiece)	28	22

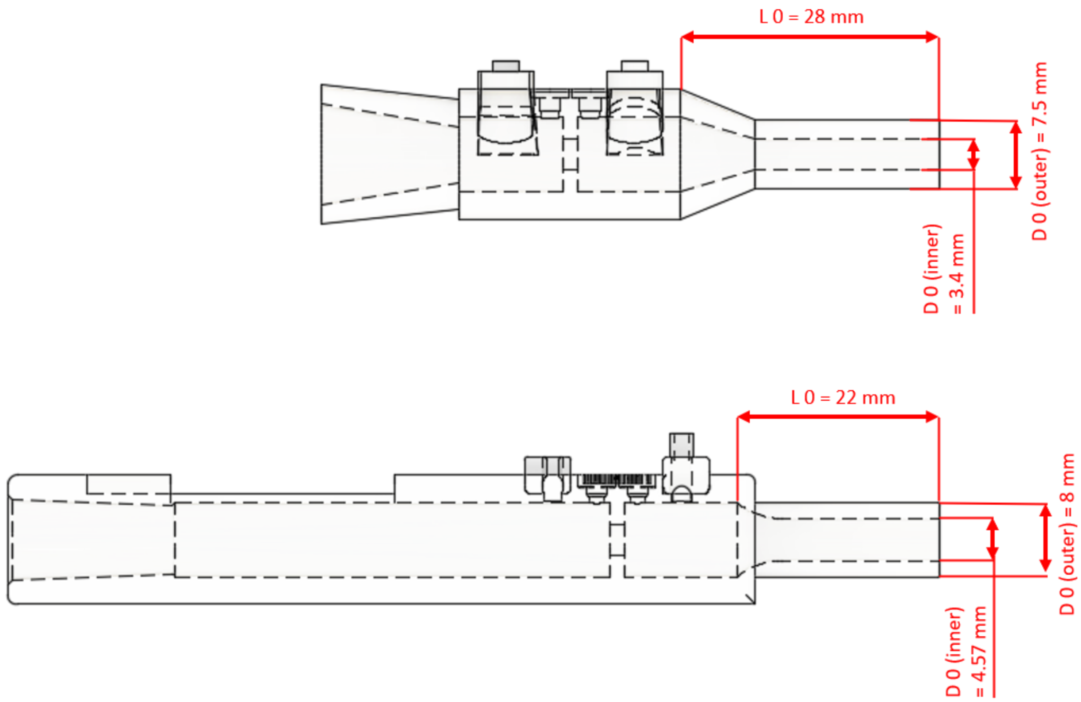


Figure 31. A side view of the mouthpiece used in the IQOS monitor at the work (top) and a side view of the mouthpiece used in the cigarette Gen (3) monitor (bottom).

4.1.2.2 Orifice chamber - FIXED

The design requirements for the IQOS monitor included specific fixed dimensions from previous monitor designs. The IQOS monitor employed the orifice chamber used by Gen 3 because it is tested and functions well. The orifice diameter (**D orifice**), the thickness of the orifice (**T orifice**), and the diameter of the inner channel (**D1 = D 2 (D inner))** were all fixed. The channel's length before **(L1)** and after **(L2**) the orifice could be adjusted. The variable names and numbers from the Autodesk Fusion 360 are shown in **Table 5** and **Figure 32.**

The mouthpiece attachment we used for the IQOS monitor is the exact flow path dimensions used for Gen3 cigarettes in OS4. Even though the outer shape was rectangular in cigarette Gen 3, while the mouthpiece is the cylindrical outer shape for IQOs, the orifice chamber has the exact dimensions. The Diameter of the orifice is 3.4 mm for both, and the thickness of it is 1.5 mm for both. The inner diameter before and after the orifice plate was 8 mm in Gen 3 and IQOS. Without affecting the monitor's functionality and the temptation to make it smaller, we kept the inner diameter D1 = D 2 (D inner) 8 mm. Still, we changed the tube length before and after the orifice. The length of the inner channel before the orifice (L1) was 13 mm in Gen 3, and it changed to 12 mm in IQOS (the new length of 12 mm, which is the shortest proper length for the mouthpiece), while the length of the inner channel after the orifice (L2) was 48 mm in Gen 3 and changed to 12 mm in IQOS.

Table 5. The dimensions of the orifice chamber in IQOS and Gen3 are all in (mm).

Name	**IQOS**	**Cigarette Gen 3**	
D orifice	3.4	3.4	Fixed
T orifice	1.5	1.5	
D1 = D 2 (D inner)	8	8	
L1	12	13	Unfixed
L2	12	48	

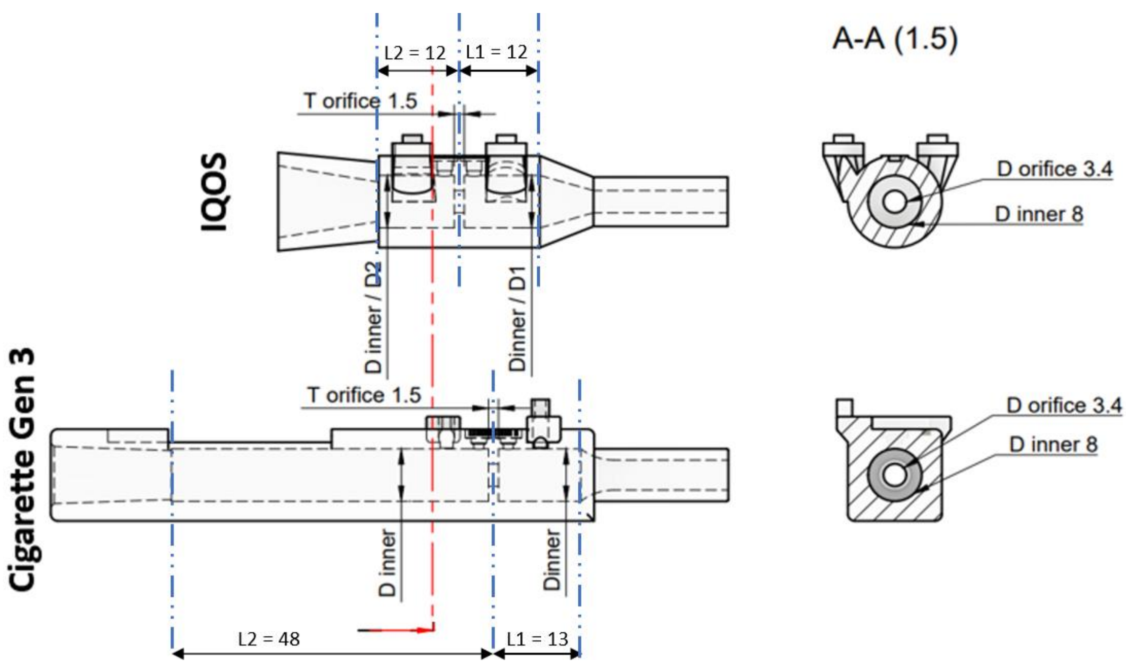


Figure 32. The drawing of the critical dimensions of the orifice chamber, all in (mm).

4.1.2.3 Pressure Sensor Seating - FIXED

The IQOS monitor design required that we incorporate the exact sensor board seating dimensions of previous wPUM monitors. **Table 6**, **Figure 32** and **Figure 33** show the sensor board seating dimensions for IQOS, the cigarette Gen 3 wPUM monitor, and the Juul wPUM monitor. There are two crucial dimensions to get a good sealing with the sensor board: the thickness of the pressure sensor package above the board (Stand-off depth) and the diameter of the posts (D post).

Table 6. The sensor board seating dimensions in IQOS, Gen 3, and JUUL.

Name	**IQOS**	**Gen 3**	**JUUL**	**Description**
Pressure Tap Seating				
LP1P2	4.4	4.4	4.3	Distance between pressure taps' centers
Oring's room	4	4	4	The outer diameter of o ring
Oring's housing	0.8	1.4	0.8	The space where the O ring will be placed
L barb	2.3	2.3	2.3	Length of pressure sensor
L pt	3	3	4.24	The pressure sensor tap's depth
D pt	2	1.91	2	The pressure tap's diameter
Sensor Board Seating				
+ Lxsb (Not from fusion)	7	7	7	The distance from the center of the posts to the orifice in +X direction.
- Lxsb (Not from fusion)	7	7	7	The distance from the center of the posts to the orifice in -X direction.
+ Lysb (Not from fusion)	7.65	7.65	7.65	The distance from the center of the posts to the orifice in the +Y direction
- Lysb (Not from fusion)	6.35	6.35	6.35	The distance from the center of the posts to the orifice in the -Y direction
D post	2.87	2.6	2.87	diameter of sensor board mount holes
Stand-off depth	1.91	1.9	1.91	Thickness to PS package above board

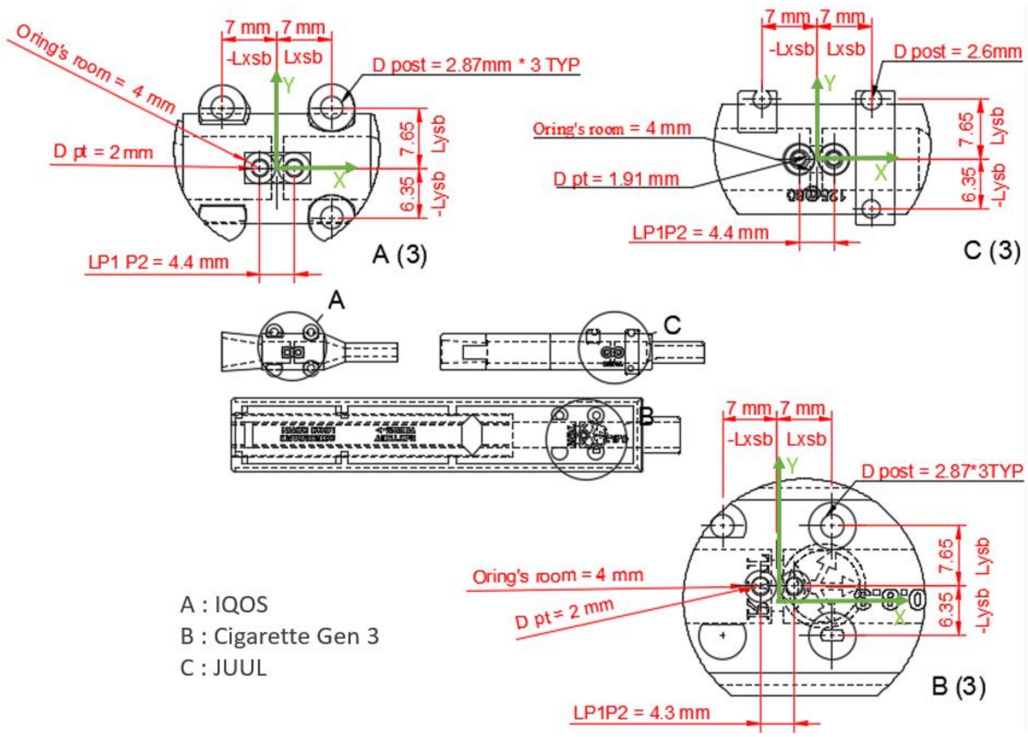


Figure 33. Sensor Board Seating (Top View) for IQOS, Cig Gen 3, and JUUL

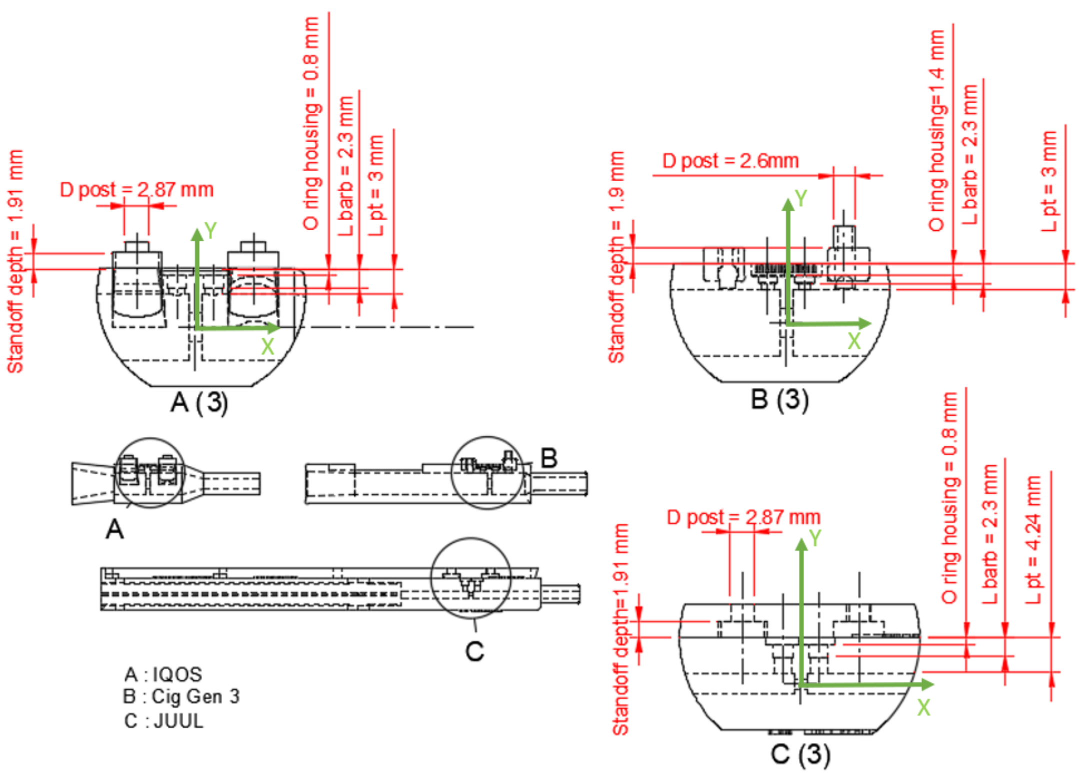


Figure 34. Electronic Boards Seating (Side View) for IQOS, Gen 3 and JUUL

4.2 PRODUCT ATTACHMENT DESIGN.

We made this part out of two sub-designs to achieve the requirements. The holding attachment design has two parts: the holder for holding the IQOS PCU and the interface for holding the heat stick.

4.2.1 Requirements

1. **Easily Inserted:** The heat stick easily fits the attachment mouthpiece.
2. **Holding:** Good strong hold on the heat stick so it doesn't slip out during use.
3. **Easily Removed:** Should allow the heat stick to be removed "easily", where easily could be defined as:
    i. **Best case**: can remove the heat stick by pulling on the PCU.
    ii. **Second best case**: the heat stick stays in the monitor when pulling on the PCU.
    iii. **Worst case**: the heat stick falls apart when trying to take it out of the monitor.
4. **No Leaking:** Give a good sealing of the heat stick and the orifice chamber.
5. **Do not disturb airflow:** Minimize the blocking of the airflow through the IQOS.
6. **Heat stick placement stop:** Ensure the heat stick doesn't get inserted too far in.
7. **Minimize the monitor size.**
    i. Minimize the overall length of the orifice chamber.
    ii. Minimize the overall length of the monitor.
8. **Maintainable**:
    i. Easily use
    ii. Easy to clean
    iii. Low-complex
9. **Lightweight**
10. **Familiar Ergonomics**: Handheld form factor mimics the shape of IQOS.
11. **Affordable printing**
12. **Activation Button Access:** Expos IQOS activation button and Easy to hit the button
13. **Aesthetic**
14. **Durability**

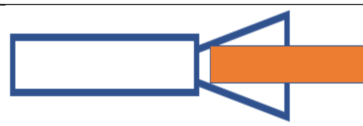
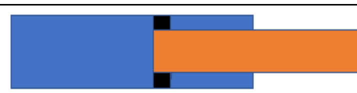
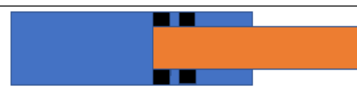
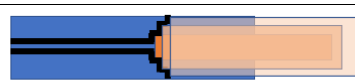
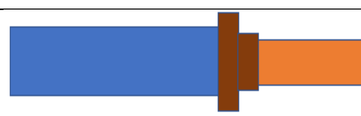
4.2.2 Interface

This part's function is to create a seal between the tobacco product and the monitor and direct the aerosol from the product to the orifice chamber.

4.2.2.1 Brainstorm

The following are the initial ideas for the interface. **Table 7** shows the different ideas for the interface design based on the various ways to support and accept the heat stick.

Table 7. Interface's brainstorm ideas for attaching the heat stick to the monitor

Interface ideas' names	**Image**	**Examples**
1. Press fit		• SPA monitor • IQOS prototype wPUM monitor
2. Cone-Shaped		• CreSS monitor • Gen 3 cigarette monitor
3. Single O-ring		Ciga-like wPUM monitor
4. Double O-ring		
5. Stair mouthpiece		
6. Orange O-ring		

4.2.2.2 Evaluation and Choose

Interface's criteria are evaluated by ranking them from 1 to 5. Number 1 is the worst (low efficiency), (and 5 is the best). The higher number from the criteria was for number two (Cone-Shaped). The option selected for the IQOS monitor is number two (Cone-Shaped), as shown in **Table 8.**

Table 8. Interface's evaluation table

N	Design's name	(1) Easily inserted	(3) Holding	(2) Easily removed	(4) No Leaking	(5) Do not disturb the airflow	(6) Heat stick placement stop	(7) Minimize monitor size	(8) Maintainable (Low complexity)	Total
1	**Press fit**	3	1	4	2	4	1	5	5	25
2	**Cone-shaped**	5	3	3	3	5	4	5	5	33
3	**Single O-ring**	2	4	2	4	3	2	5	2	22
4	**Double O-ring**	1	5	1	5	2	3	5	1	23
5	**Stair mouthpiece**	4	2	4	2	1	5	5	3	26
6	**Orange O-ring**	4	5	2	5	4	1	4	5	30

4.2.2.3 Manufacturing Variability of the Heat Stick

Figure 35 shows the experiment's procedure. We used calipers to take repeated measurements of several heat sticks and estimate the mean and standard deviation of the heat stick diameter. Half a pack of heat sticks (10 Heat sticks) was used; see **Figure 36**.

- **Procedure for determining the heat stick's diameter in this experiment:**

1. Hold the heat stick in a vertical position.
2. Use the calipers to measure the diameter at about 3mm from the filter end of the heat stick **Figure 37**.
3. Record the reading in the Excel sheet.
4. Release the calipers and drop the heat stick on the table.
5. Redo steps 1- 4 two times to make two additional repeated measurements of the diameter of the same heat stick.
6. Redo steps 2-5 for all heat sticks included in the test (total 10).
7. Find the mean and the standard deviation for the whole sample.
8. Redo the same steps for the distance 20 mm from the tip of the heat stick.

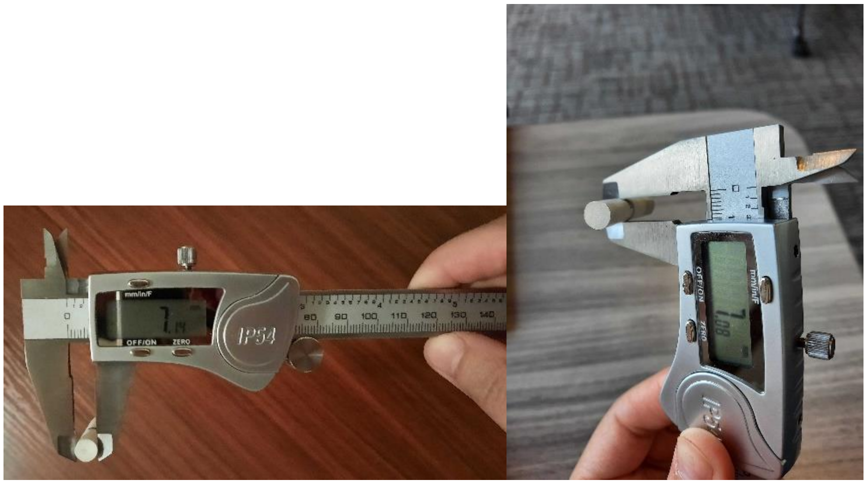


Figure 35. Using the caliper to measure the diameter of the heat stick, (left) is displayed at 3mm from the tip, and (right) is at 20 mm from the tip.

Figure 36. The number of heat sticks that were used in the cone shape design experiment

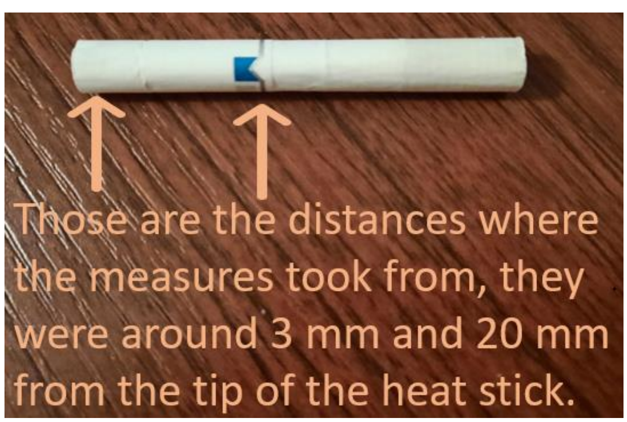


Figure 37. The distances on the heat stick from which we measured the diameter during the experiment.

- The exact steps of the experiment were done to measure the length of the heat stick.
- The exposed part of the heat stick after inserting it into IQOS (19.87 mm), as shown in **Figure 38.**

Figure 38. Exposed part of the heat stick after being inserted into IQOS

The results: The heat stick measurements were obtained in the laboratory from the experiment. The diameter in the experiment is measured from two different distances: the first was 3 mm from the tip of the heat stick, and the second was 20 mm from the tip of the heat stick. The mean of the heat stick's diameter (DHT mean) was 7.245 mm, with a standard deviation of 0.069 mm. DHT mean is considered the 7.245 mm diameter of the heat stick (DHT). As shown in **Figure 39,** the standard deviation was added before and after the DHT. We multiplied the standard deviation by a factor of three to increase the accuracy.

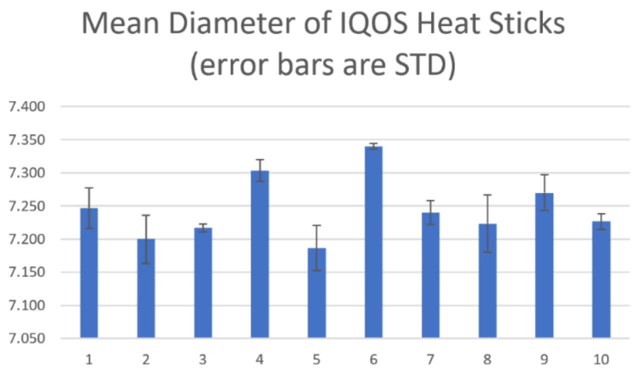


Figure 39. The mean diameters of the heat sticks with the error bars

4.2.2.4 Design

After using the heat stick, we discovered that the heat stick's diameter is less than that of the combustible cigarette. We added another feature called "product attachment" to stop the heat stick from inserting inside the channel. The product attachment is an insert cone to help the heat stick easily reach the proper place, as shown in **Figure 40** and **Table 9**. The function of **(D stop)** is to prevent the heat stick from being in the inner channel and blocking the airway inlet. The outer diameter of the insert cone **(D insert)** helps the product to be easily inserted. The insert cone is designed to have a bigger diameter than cigarette Gen 3 because the heat stick is supposed to be in the IQOS device, and the user will push the device with the heat stick within it to the monitor. The length of this cone is called **(L4). Figure 41** and **Table 10** show all Interface design steps calculating and the dimensions we used for this calculation.

Table 9. The differences in the critical dimensions for the interface cones design in IQOS (top) and cigarette Gen 3 (bottom)

Feature	IQOS	Cigarette Gen 3
D stop	6	5
D insert	11	9.75
L4	15	18

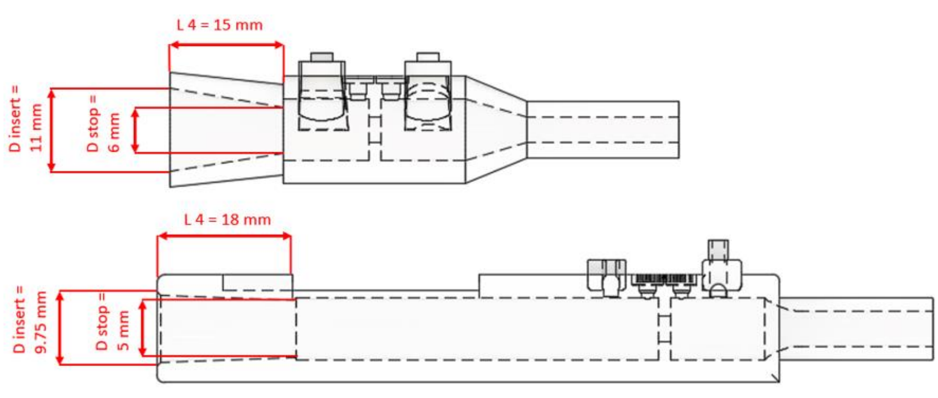


Figure 40. The dimensions of the product attachments for IQOS (top) and cigarette Gen 3 (bottom).

Table 10. Interface measurements table

Name	Value	Expression
DHT (D mean)	7.245	Mean D Heat stick from Excel
STD of DHT	0.069	This is the standard deviation of the heat stick diameter from Excel
L stop	3.736	The distance from D stop to D mean
L4	15	L cone the distance from D insert to D stop
Ø°	9.46° degrees	The slope of the cone to the horizontal line.

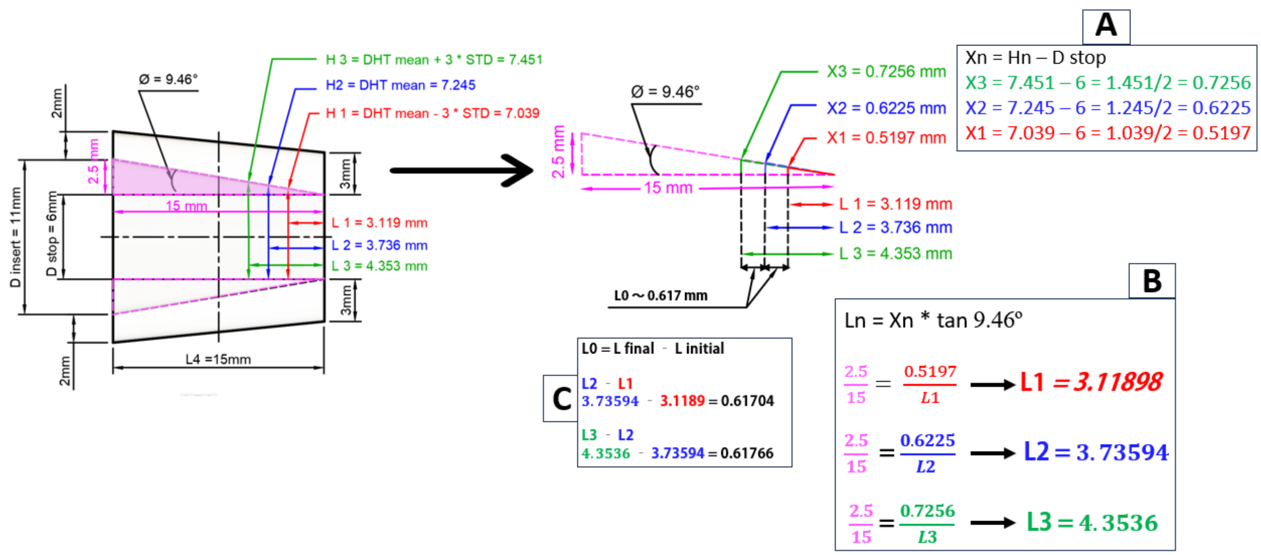


*Figure 41. The calculations for the Interface design. The picture has three different colors, each referring to the size of a distinct triangle. The Rectangle shape called "A" shows the vertical distances for each triangle, while "B" shows the horizontal distances. The rectangle "C" demonstrates the differences in the distances before and after the DHT mean, representing the 3*STD.*

4.2.2.5 Test

Two prototypes were measured to test the cone's inside diameter and determine the best size diameter for the D stop. DHT mean was measured as described in the section, (Manufacturing 4.2.2.3). The test concluded using different sizes of gauge pins and finding the closest pin, which had to be stuck inside the D stop and didn't enter the orifice chamber unless we pushed hard on it. This was considered the best case for the printed part. Each gauge was 0.001 inches (0.0254 mm) different in measuring, as shown in **Figure 42**. In **Table 11**Prototype 1 was designed at a 7 mm D stop, and prototype 2 was designed at a 6 mm D stop. The FabLab 3D printer uncertainty is ± 0.0005in (0.0127mm), so those two prototypes are not precisely 6 mm or 7 mm.

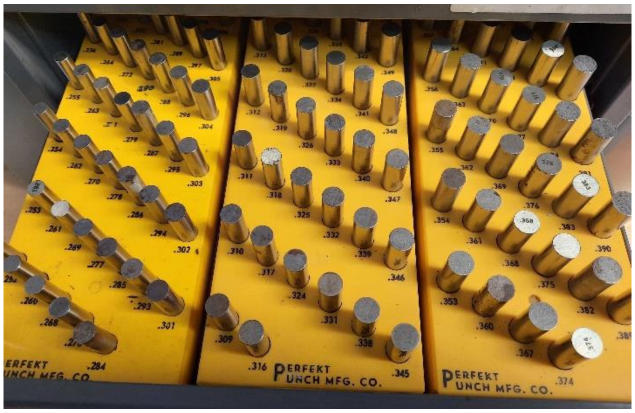


Figure 42. The gauge pin tray test is used to measure the inner diameter of the interface cone.

Table 11. Pin sizes for testing the D stop of the prototypes

Pin diameters for prototype 1 testing	**Pin diameters for prototype 2 testing**
1. The cylinder of 0.273 in diameter (6.934mm) does not enter the orifice chamber. 2. The cylinder of 0.272 in diameter (6.909mm) does not enter the orifice chamber unless with a hard push. 3. NA 4. The cylinder of 0.271 in diameter (6.883mm) enters easily into the orifice chamber.	1- The cylinder of 0.232 in diameter (5.893 mm) does not enter the orifice chamber. 2- The cylinder of 0.231 in diameter (5.867 mm) does not enter the orifice chamber unless with a hard push. 3- The cylinder of 0.230 in diameter (5.842 mm) enters the orifice chamber with an easy push. 4- The cylinder of 0.229 in diameter (5.817mm) enters easily into the orifice chamber
 *Figure 43. Prototype 1 in the gauge pin test was designed with a Dstop=7 mm*	 *Figure 44. Prototype 2 in the gauge pin test was designed with a D stop =6 mm*

The measured value for the D stop for prototype 1 was 6.909 mm, which was too close to the criteria for DHT, which has to be less than 7.039 mm. As the number of this pin was almost the size of the squishy heat stick diameter, we decided to make the D stop smaller.	The measured value for the D stop for prototype 2 is 5.867 mm, which better meets the criteria for DHT, which has to be less than 7.039 mm.

In conclusion, we designed D insert = 11 mm since it needs to be larger than DHT to facilitate heat stick insertion. We signed D stop = 6 mm because it must be smaller than DHT-3*Standard deviation (7.039mm) to prevent heat sticks from entering the orifice chamber.

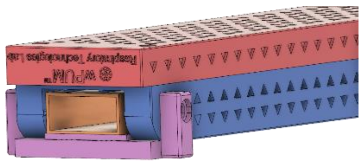
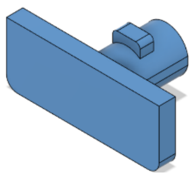
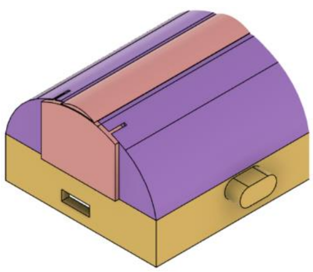
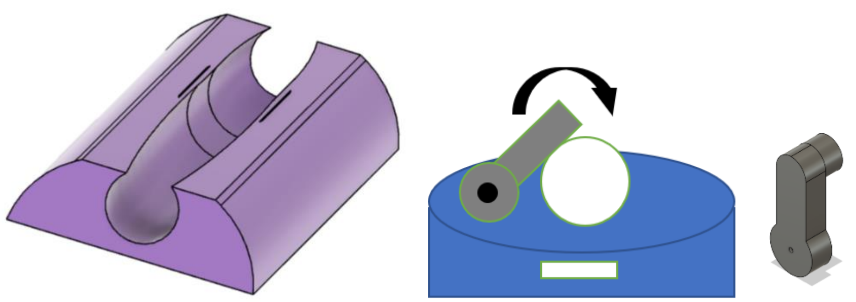
4.2.3 Holder

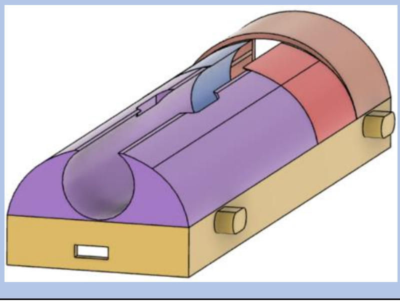
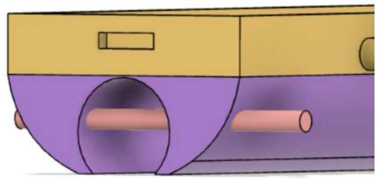
The holder is the second part of the product attachment design. This part is considering a new addition to the monitor's design functions. Using the interface component alone, as RTL did with the prior wPUM monitors, was insufficient to meet the requirements for the product attachment. This component was essential to the IQOS monitor Because the IQOS device construction consists of two parts— the heat stick and the PCU—. While the interface is designed to hold the heat stick, this part of the product attachment holds the IQOS's PCU.

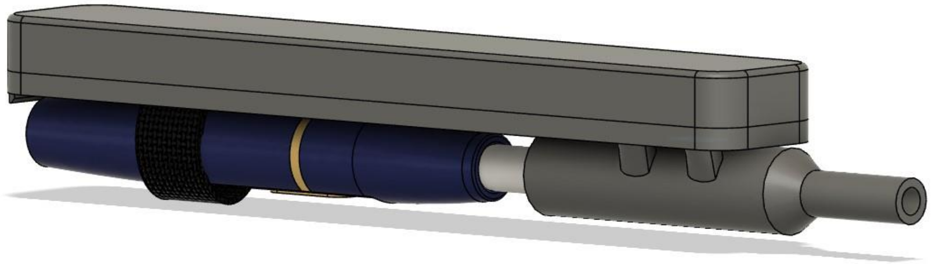
4.2.3.1 Brainstorm

The table below contains the basic ideas with the names and pictures of the holder design.

Table 12. Brainstorming ideas for the holding attachment with pictures.

N	Holding ideas	Image
1.	Closed Cavity with hinged door	
2.	Cavity with Rubber Plug and notch	
3.	Open cavity with Plug and pin	
4.	Mimic the IQOS shape using hard material with a fixed roller plug	 This figure illustrates the inner cut, which is identical to the IQOS, approximately an oval shape

5.	Mimic the IQOS shape by using soft materials to grip the IQOS	
6.	Mimic the IQOS shape using hard material with the user's finger to hold the IQOS.	
7.	Mimic the IQOS shape using hard material with an Elastic bar to hold IQOS.	
8.	Mimic the IQOS shape using hard material with a pad inside the body holder.	

9.	Mimic the IQOS shape using hard material or an open cavity with rubber buttons and holes.	
10.	Open cavity using a stick band	

4.2.3.2 Evaluation and Choose

The design of monitors was impacted by comments and survey answers from colleagues and prior Respiratory Technologies Lab research participants who used topographical monitors. Criteria are evaluated by ranking them from 1 to 5, where (1) is the worst (low efficiency), and (5) is the best (high efficiency). **Table 13** Shows the results of evaluating each design against the design requirements. The chosen design was number 5, “Mimic the IQOS shape by using soft materials to grip the IQOS”.

Table 13. Holder's evaluation table

N	Criteria	(14) Durability	(4) No Leaking	(7) Minimize the size	(8) Maintainable	(8i) Easily to use	(8ii) Cleaning	Total
1.	Closed Cavity with hinged door	2	3	2	3	4	1	15
2.	Cavity with Rubber Plug and notch	3	4	4	3	2	1	17
3.	Open cavity with Plug and pin	3	4	4	1	5	1	18
4.	Mimic the IQOS shape using hard material with a fixed roller plug	4	3	5	5	5	1	23
5.	Mimic the IQOS shape by using soft materials to grip the IQOS	3	4	5	5	4	3	24
6.	Mimic the IQOS shape using hard material with the user's finger to hold the IQOS.	5	2	5	5	4	2	23
7.	Mimic the IQOS shape using hard material with an Elastic bar to hold IQOS	1	2	4	5	2	3	21
8.	Mimic the IQOS shape using hard material with a	4	1	2	2	4	1	14

	Pad inside of the body holder							
9.	Mimic the IQOS shape using hard material with rubber buttons with holes	2	3	3	3	4	4	19
10.	Open cavity with using a stick band	2	2	4	4	3	5	20

4.2.3.3 Design

This part is replaceable. The inner shape of this part mimics the IQOS's PCU. The holder was built with a rounded top to provide aesthetic access to the PCU's button. The holder allows access to simulate pressing the original button because the IQOS begins operating as soon as the user presses the button.

There are two mechanisms used to attach this holder to the electronics housing: first, the two hooks receptors, and second, the rods, as shown in **Figure 45** and **Figure 46**The two hooks' receptors accommodate the hooks on the electronics housing, ultimately keeping the holder from moving up and down. The two rods prevent the holder from rotating. The holder uses a partial slide mechanism to insert the rods in the channel and push the holder all the way to the end to insert the hooks' receptors.

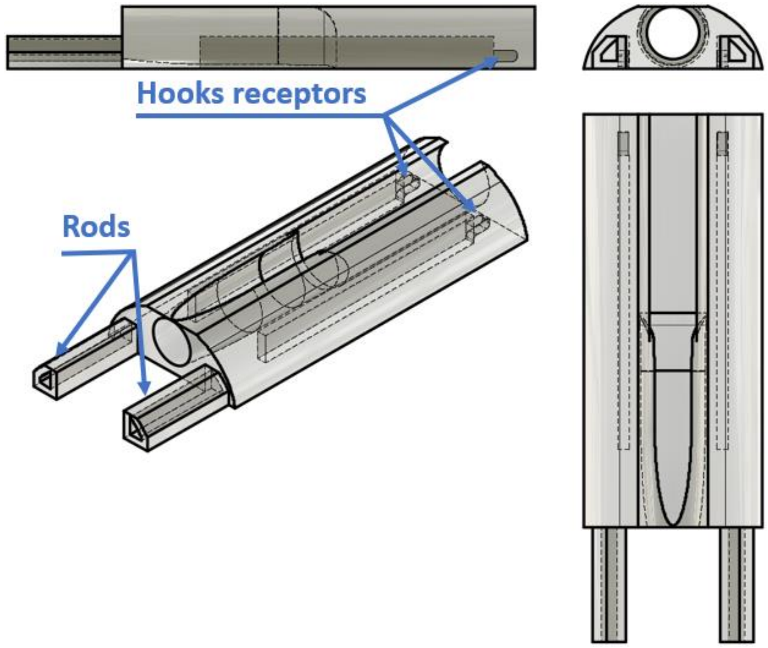


Figure 45. Different views show the holder. The blue points are the two mechanisms for attaching the holder to the electronics housing part.

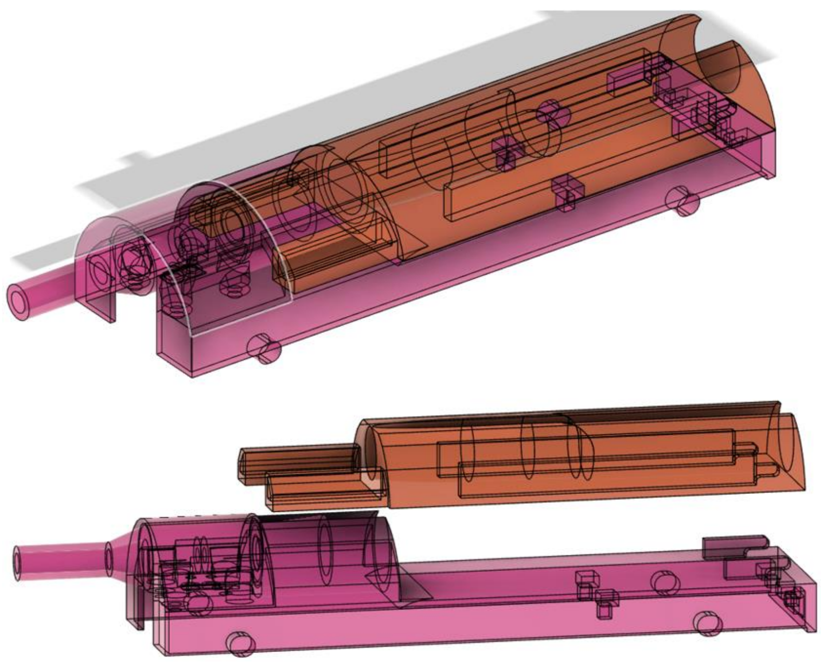


Figure 46. The method of attaching the holder to the electronic housing uses hooks, receptors, and rods.

4.2.3.4 Build

The holder was made of flexible material to achieve an appropriate IQOS holding mechanism. The holder was printed with the following materials: The iterative design was printed at RIT's FabLab, where they could afford the Flexible resin SLA (80A) material. The final design is produced by TriMech, which can produce several levels of durability, although not (80A).

Figure 47 illustrates TriMech's durability range; the most durable material is Shore A 95 (Shape "A"), and the most fixable material is Agilus 30 (Shape "D" in Figure 46). We printed the holder at Shore A 70 (Shape "C" in Figure 46) at TriMech, but it was so soft, and it was affecting the heat stick. That is why we reprinted the part as a second trial using shore A 85 (Shape "B" in Figure 46). For the test purposes, we chose shore A 85 (Shape "B" in Figure 46) as the most effective durability for this part. We used Shore A 85 on the TriMech Polyjet machine with a tolerance of +/-0.012" up to 4" and +/-0.003" for every inch after that. The option "No finish" was opted for this part because the finishing process may change the material's properties. The cost of printing that part was $106.93. The friction between this material and the PCU keeps the PCU from falling. The flexible material is tightly held in the IQOS to facilitate easy insertion and prevent it from falling.

Figure 47. A sample piece has different Polyjet machine shore values that TriMech can afford.

4.2.3.5 Test

The design requirements were used to test this part. This material offered a high degree of durability while being aesthetically pleasing. This component performed well in holding the PCU in place, preventing it from falling out, and enabling the access button to function without issue. Due to its rounded top, this element was recognizable in terms of ergonomics as the IQOS. This part was built to meet the lightweight needs with a cavity responsive in front of the hooks and inside the rods. The test successfully met the condition that the heat stick could be simply inserted into the PCU and removed without causing damage to the heat stick by pulling on the PCU. In this part, the air inlet was good enough to prevent blocking, leaking, or disturbing the airflow.

4.3 The Electronics Housing Design

The electronics housing chamber is considered as a monitor's body. The general functionality of this part is to fit the electronics precisely and protect them. The external form of the electronics housing is primarily determined by the characteristics of the products and the electronics to be used within the electronics housing. Due to its bigger battery, the IQOS container is wider than comparable monitors, even though the size of the IQOS PCU is small.

4.3.1 Requirements

These are the requirements of the electronics housing:

1. **Assembly accommodation**: Must accommodate the electronics assembly Gen 3 (A+)
2. **Battery accommodation**: This monitor must accommodate a bigger battery (1200 mAh)
3. **Has USB access:** Provide access to USB for recharge and data transfer
4. **USB support**: This feature helps secure the main board in place while the USB cable is connected and disconnected.
5. **Pressing on the pressure sensor board**: The pressure pad is used to apply pressure on the pressure sensor board to ensure proper sealing between the pressure taps and mouthpiece.
6. **Has access to core board buttons:** Provide access to power and reset buttons on the core board.
7. **Do not damage the electronics:** Minimum interference with internal components (sensor board, battery, ribbon cable, main board). In previous monitors (JUUL), the lid touched internal components during opening and closing, which could cause damage.
8. **LED sight**: Allow line of sight to the LED to indicate monitor status to the user.
9. **Durability**: low break potential and smooth
10. **Lightweight**
11. **Complexity**: Easy to use

    VII. Easy to clean

VIII. Low complex
IX. Smooth
X. Consider IQOS shape and size
XI. Ergonomic for technician and user

12. **Minimize the size**: Use a slim design and use as minimal material as possible.

4.3.2 The Chamber

Besides the easy access requirement to the button, it is easily maintainable. This monitor was made to accommodate the Gen 3 (A+) and 1200 mAh battery. The two critical dimensions in the core board seating are the inner length and the inner width of the main board. Battery width is a significant component in the electronics assembly, thus mandating the container's width. Four cubes were added to support and secure the core board in its place. This part is attached to the Mouthpiece and was made in SOMOS 11122XC material at the TriMech fabrication lab.

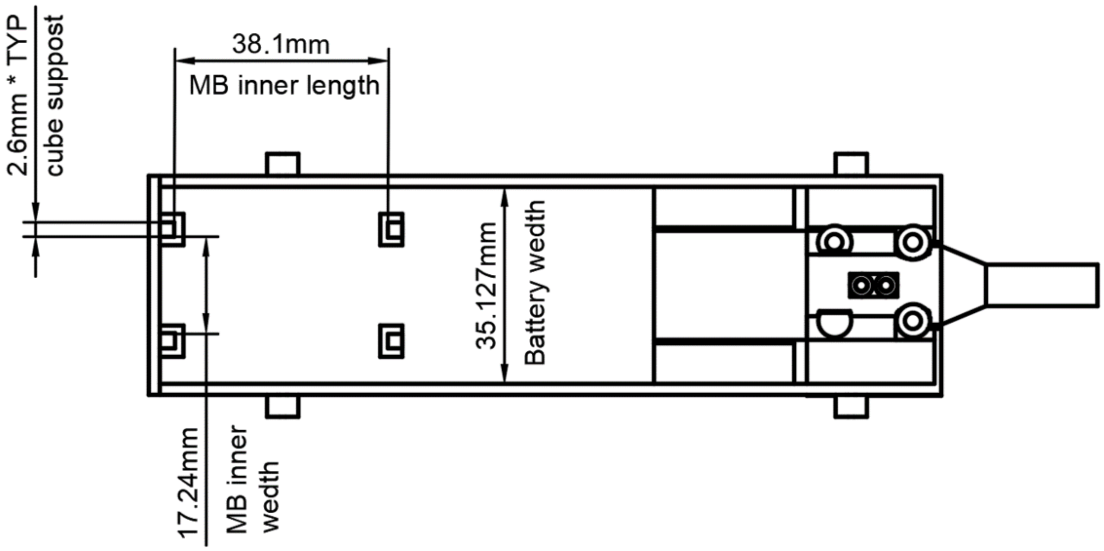


Figure 48. The chamber's inner dimensions.

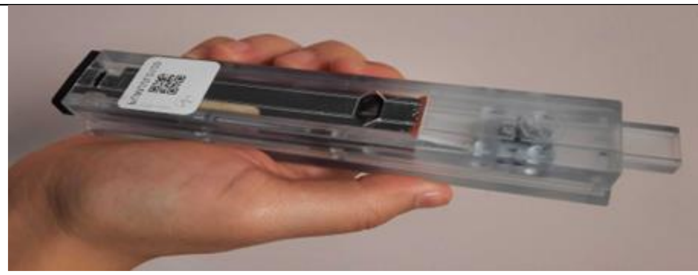
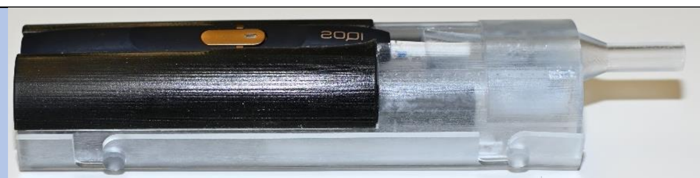
4.3.3 Lid Locking

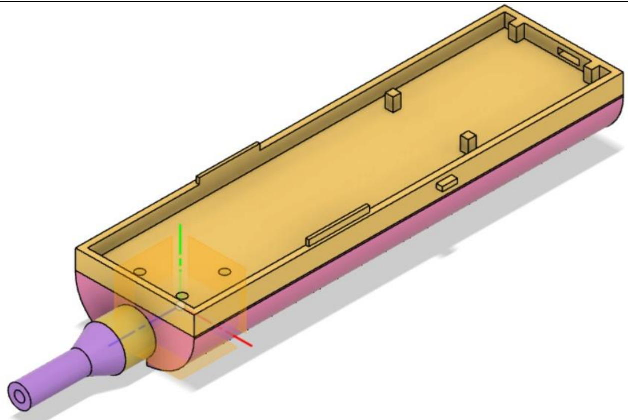
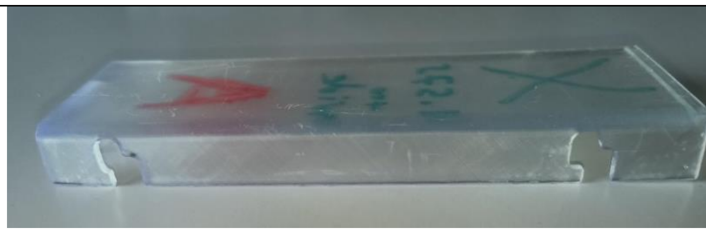
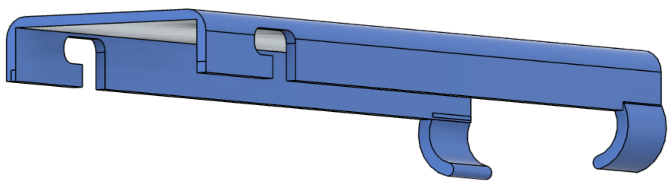
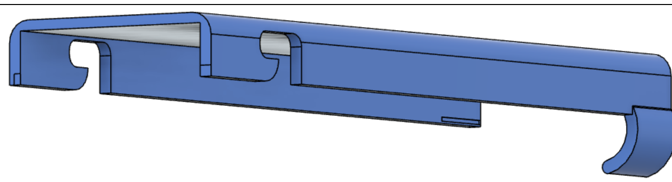
The monitor features a lid that can be removed so technicians in the lab can open it to transfer data and perform maintenance.

4.3.3.1 Brainstorm

Table 14 show the brainstorm ideas for locking mechanisms. For this monitor, number 2 from **Table 14** was chosen “Four slots and four pins connection”.

Table 14. Different ideas for lid locking with pictures

N	Product	Image	Description
1.	full rail		Current JUUL
2.	Four slot and four pin connection		IQOS design
3.	Snap	 	IQOS prototype

4.	Partial snap with hooks		
5.	Four stair slots and four pins		
6.	Two clamps and two slots		
7.	Two slots and one clamp		

4.3.3.2 Evaluation and choose

The evaluation of the lid locking's designs was based on their functionality, as shown in **Table 15**.

Table 15. The lid-locking design evaluation parameters

N	Criteria	(9) Durability	(11) Complexity	(11i) Cleaning	(5) Pressing access (on the pressure sensor)	(12) Minimize the size	(7) Damage	(6) Access to the core board	total
1.	full rail	5	1	4	5	3	3	2	23
2.	Four-slot and four-pin connection	5	1	4	4	3	4	3	24
3.	Snap	1	1	3	2	4	5	3	23
4.	Partial snap with hooks	1	1	3	2	3	4	3	17
5.	Four stairs slots	2	1	3	3	3	4	3	19
6.	Two clamps and two slots	1	1	3	3	2	4	3	17
7.	Two slots and one clamp	1	2	3	3	2	4	3	18

4.3.3.3 Design

We used the lid mechanism to keep the electronics contained. The lid mechanism works by putting the lid on the electronics housing and sliding it backward into the pins. This mechanism keeps the electronics safe and holds them secure without affecting or damaging them. As shown in **Figure 49**, the lid has four slots to hold onto the four pins of the electronics housing.

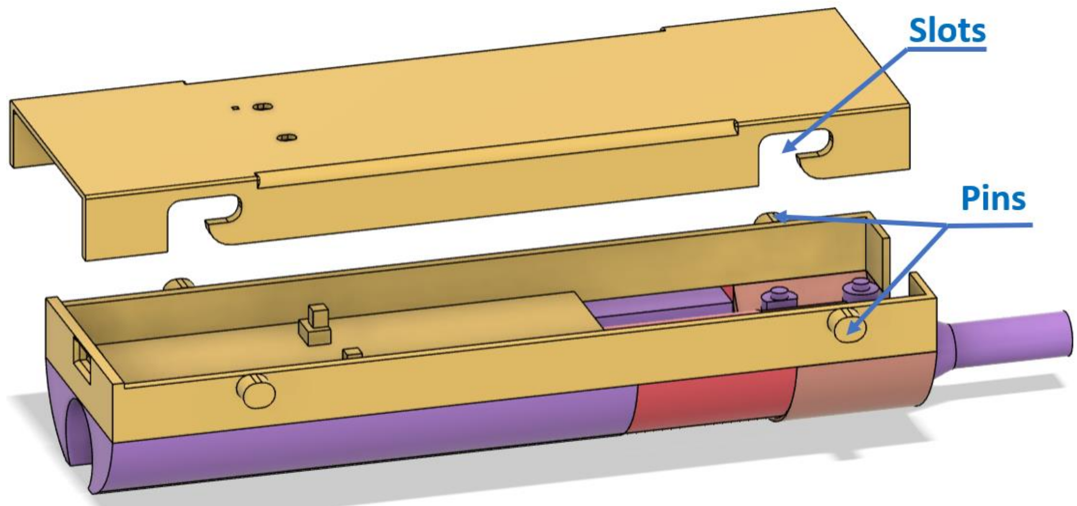


Figure 49. The slots and pins for the lid locking mechanism. The lid (top) and the electronics housing (bottom).

Following are the specifications of the lid that this monitor is using, as shown in **Figure 50**:

- The U-shape mouthpiece holder protects the electronics and the inner side of the monitor.
- The pressure pad applies pressure on the sensor board to ensure proper sealing between pressure taps and mouthpiece
- Two holes give access to the power and reset buttons on the main board.
- Light indicator allows line of sight to the LED, which indicates the user's monitoring status.
- The USB support is used to push the USB downwards and prevent the possible movement of the Core Board.

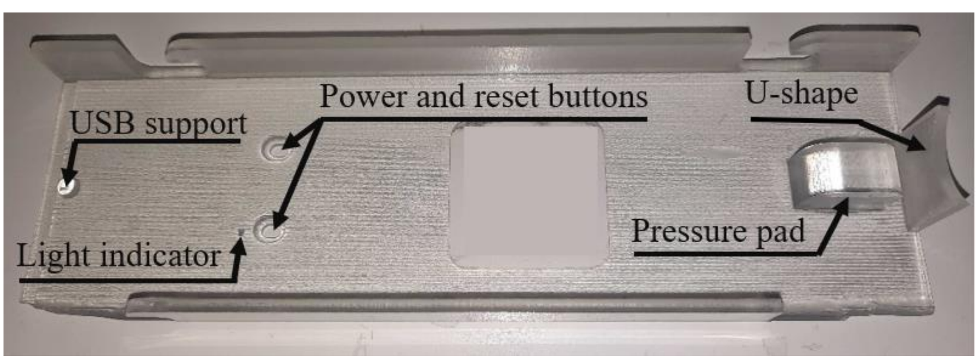


Figure 50. The specifications of the lid that this monitor is using

4.3.3.4 Build

This item was manufactured at TriMech utilizing a class 6 transparent material known as SOMOS 11122XC. Stereolithography (SLA) was used to create the part, and the natural finish had no impact on the qualities of the printed part. Each lid costs $113. Somos11122XC has been certified by the United States Pharmacopeia (USP) Class VI Testing, which assesses the "possible biological effects of polymer materials." The most stringent testing is done on polymer materials, with Class VI being the highest classification possible.

4.3.3.5 Test and Iterate

The lid-locking design *was* iterated several times. Specifically, the pressure pad dimensions, the u-shape part that protects the electronics, and the USB support, as shown in **Figure 50**. The following pictures illustrate how I iterated the lid-locking design.

Figure 51 illustrates that the case is open and the blue arrow shows where the USB support is located when the monitor is closed.

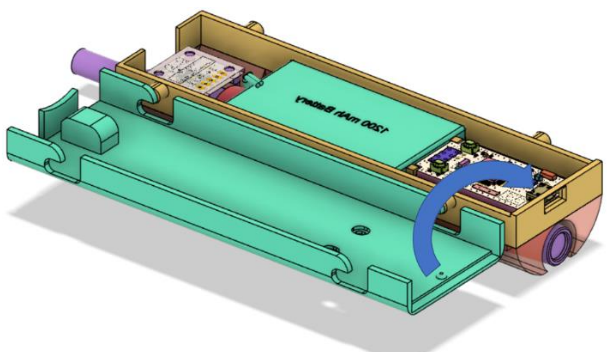


Figure 51. The location of the USB support.

In **Figure 52,** the two pictures to the left show that the u shape mouthpiece holder has increased from 9.5 mm (case a) to 13.856mm (case b) to fully protect the electronics and the inner side of the monitor. In **Figure 52, the two pictures to the right show that the USB support is made longer by 0.75mm to push the USB downwards and prevent possible movement of the core board**. In case (1), the depth was 1 mm; in case (2), it was 1.75 mm.

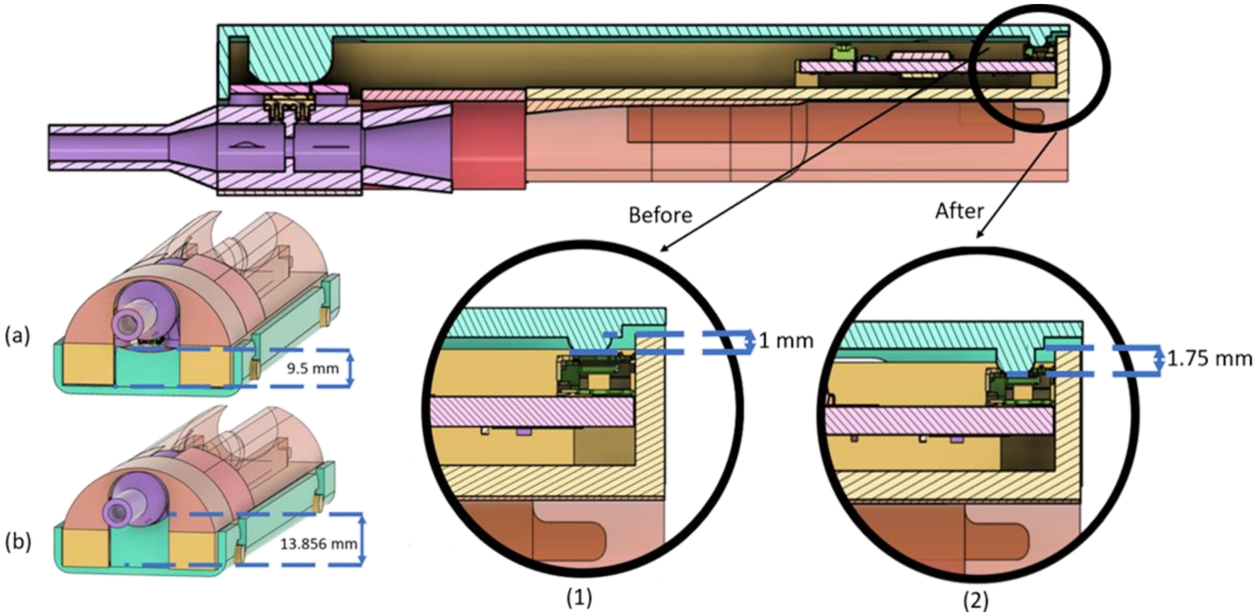


Figure 52. Iterative changes on the lid design. Pictures (a) and (b) to the left illustrate the dimensions' differences before and after the U shape mouthpiece holder adjustment. Pictures (1) and (2) to the right illustrate the difference in the dimensions before and after the adjustment of the USB support.

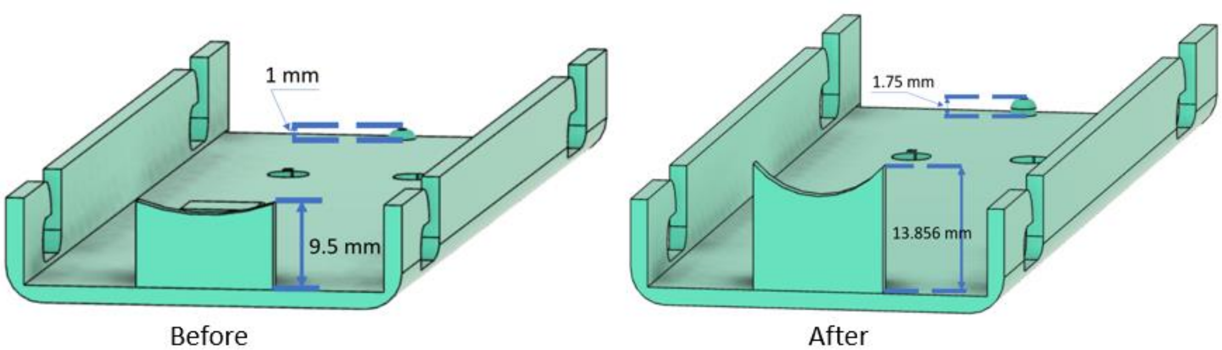


Figure 53. The dimensions before and after the lid adjustments from a different vantage point.

Figure 54 shows the function of the u shape mouthpiece holder and how it protects the electronics inside the monitor isolated from the outer environment. The picture to the left allows the airflow and dust to enter the monitor. The picture on the right shows the u shape after the adjustment and how it is protected from the impurities in the air.

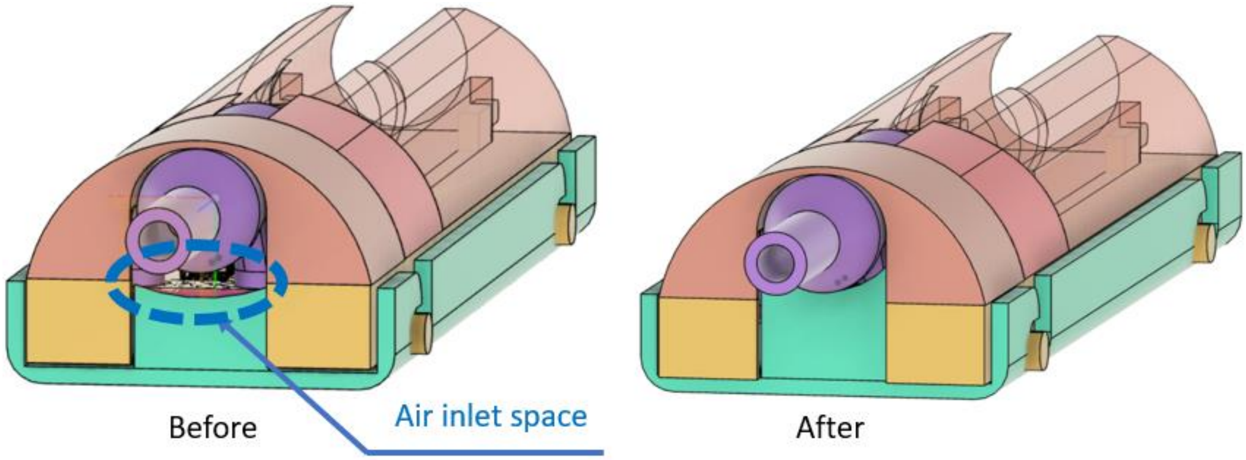


Figure 54. The inside parts and the electronics were protected by adjusting the dimensions of the u shape mouthpiece holder.

The second adjustment on the u shape mouthpiece holder was adding the fillet from the back based on the technician's opinion, as shown in **Figure 55**. This fillet should help to make this part stronger and with no sharp edges.

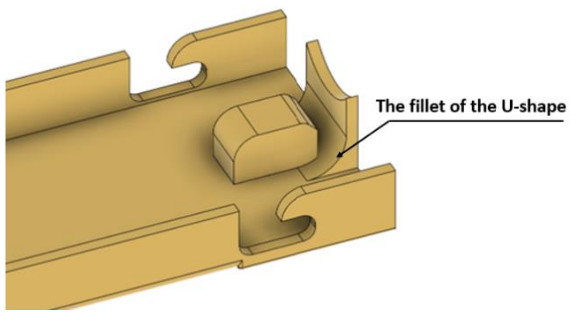


Figure 55. The fillet was added to the u-shape mouthpiece holder to increase its strength.

Some changes were made to the lid. After we printed the lid, we discovered that it had sharp edges from the inside. We adjusted the fillet by adding more material from the top of the lid to avoid breakage and make it thicker and more robust. We decreased the fillet in the whole section from 4 mm to 2 mm to improve the sharp edge inside the lid, as shown in **Figure 56**.

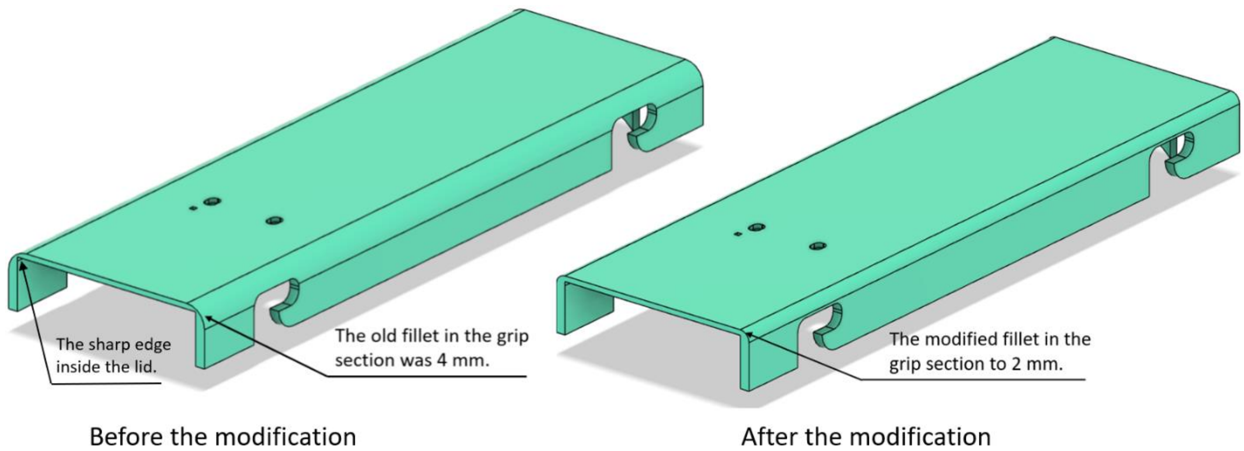


Figure 56. The left picture shows the weaker lid with the wider fillet, and the right picture shows the strengthened edge with the fillets after the modifications. We added material to the edge of the grip section by decreasing the radius of the fillet from 4 mm to 2 mm.

We added material above the slots and called them four supports, defined as 26 mm in length, as shown in **Figure 59.** On the next iteration, we increased the support from 26 mm to 30 mm to avoid the supports ending where the slots ended, which would have created areas of high-stress concentration.

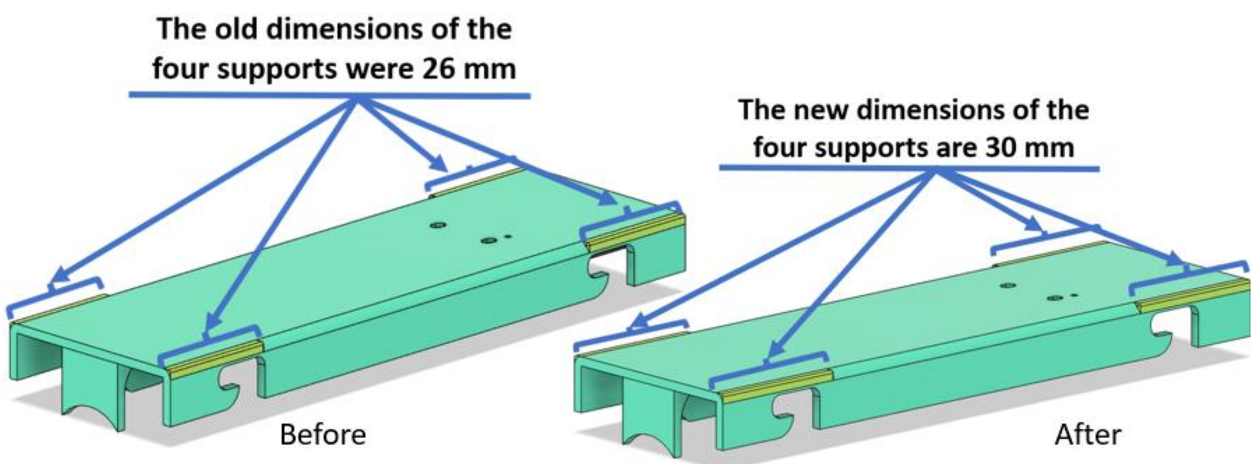


Figure 57. The old and new dimensions of the four supports above the slots. The before is on the left, and the after is on the right.

Finally, the sharp edges on other supports were softened by changing the radius from 0 to 0.5 mm, as shown in **Figure 58.** These changes are documented with the details in MEM0179.

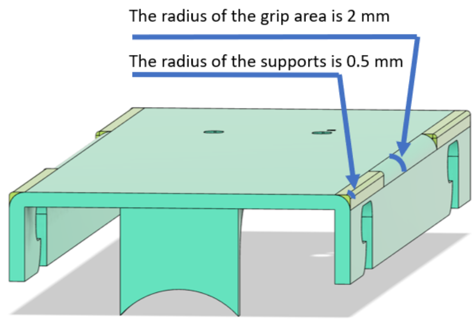


Figure 58. The different radii between the grip area and the supports.

The rest of the created area is called a grip area on the top of the lid, as shown in **Figure 59**. The radius of the grip is 2 mm, as illustrated in **Figure 58**.

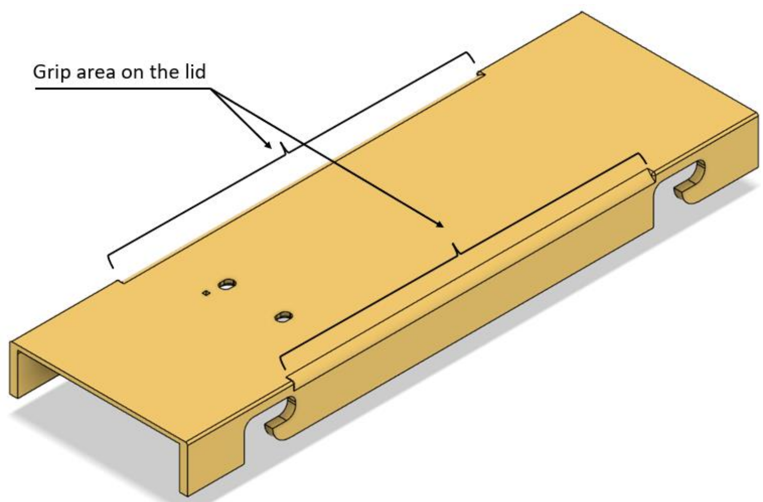


Figure 59. The grip area was created after we added the material over the slots.

The pressure pad was initially designed to be 7.746 mm in height. After the lid was fabricated, shims were used to determine whether height should be increased by 0.5 mm, and now it is 8.246 mm, as shown in **Figure 60.**

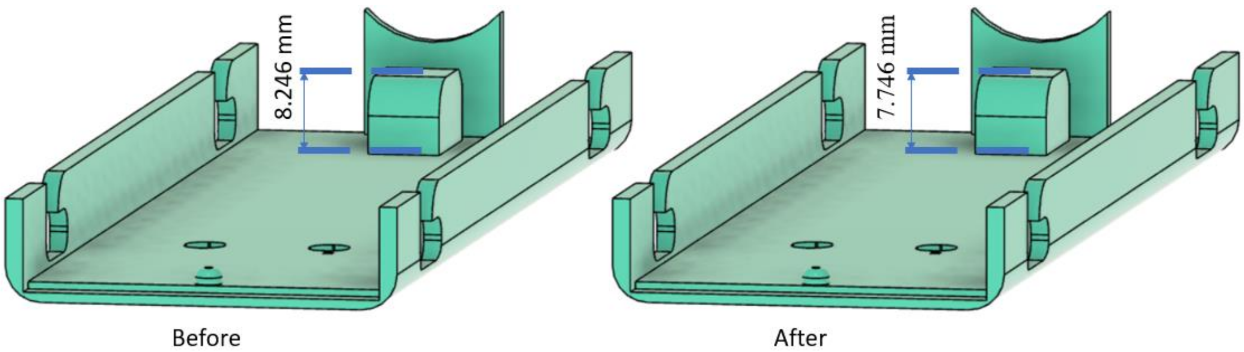


Figure 60. The height of the pressure pad

4.4 IQOS wPUM Full Assembly

Figure 61 shows the whole assembly of the IQOS wPUM monitor designed in this study. The main parts of the monitor, the mouthpiece, electronic housing, lid, and product attachment, were tested to validate that they match each other. The validation included assembling and disassembling the parts by the lab technician to ensure ease of use and reproducibility.

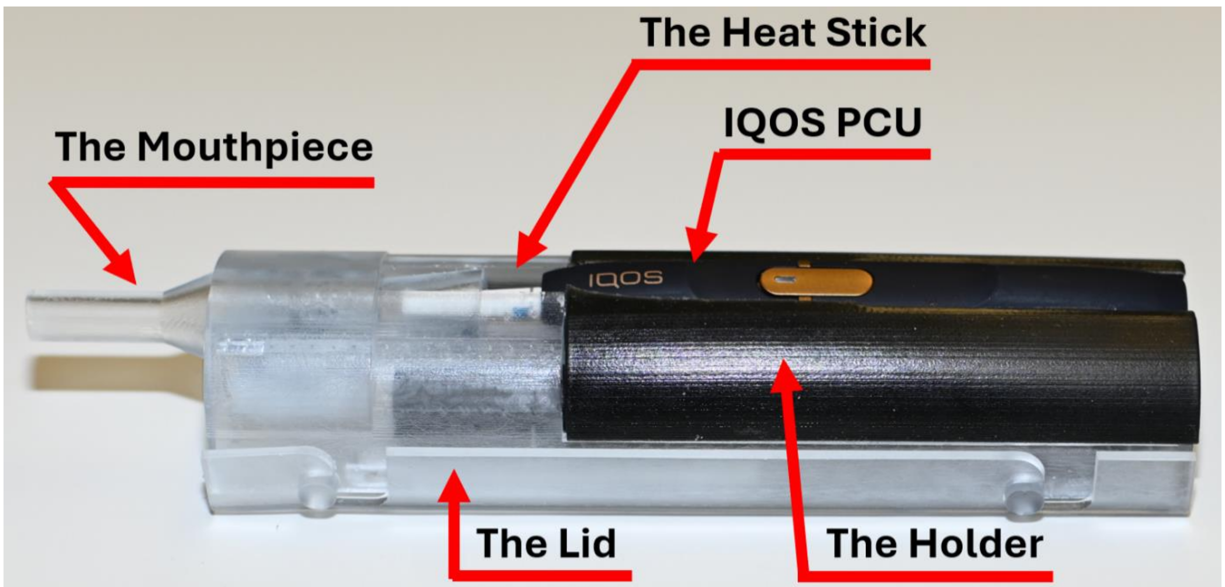


Figure 61. IQOS wPUM complete assembly with annotated parts.

The electronics assembly consists of three main components: the battery, core board, and pressure sensor board, as shown in **Figure 62**. Those electronics were designed by RTL and used in Gen 3 monitors. The core board and the pressure sensor board used to be connected by using wires in the previous versions of the monitors. In contrast, this monitor switched to using the ribbon cable to connect the same electronics. The ribbon cable was initially 4 inches long; however, it could be shortened to 3 inches based on the length of the chamber design. For the first time, this monitor uses a bigger battery (1200 mAh) than the ones we used for the other monitors (350 mAh and 650 mAh), as shown in **Figure 63.**

Figure 62. The disassembled monitor, the electronics assembly of 3 inches (top), and the electronics housing (bottom).

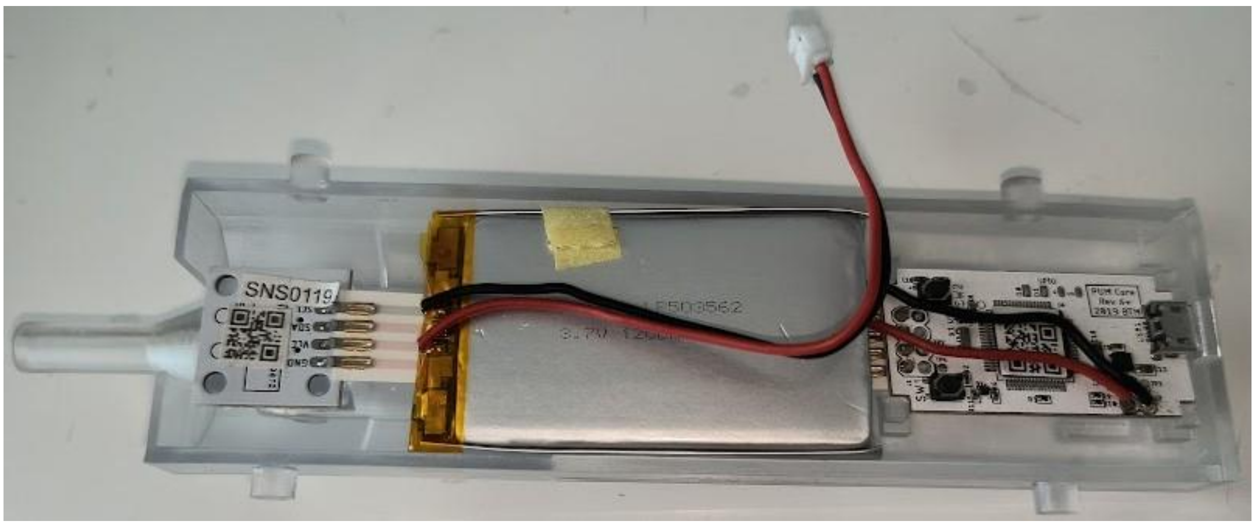


Figure 63. The electronics assembly and the 1200 mAh battery inside the electronics housing.

5 CONCLUSION AND RECOMMENDATIONS

5.1 CONCLUSION

Public health concerns were raised by the wide range of tobacco products being introduced into the market and their rapid expansion, as well as the absence of effective mechanisms for monitoring the people who use them. Since tobacco products are constantly changing, efforts must be extended to include developing new monitors or adjusting existing ones. Even though each product had a unique form and function, RTL could still monitor various items because individual monitors were designed to fit each unique tobacco product. This thesis developed the first monitor designed to monitor IQOS 2.4 manufactured by Philip Morris.

There are a few processes that tobacco products must undergo before designing the monitor. I started outlining a structured process for designing topography monitors, focusing on user needs and iterative improvement. The first step is to concentrate on users' demands to enable users to utilize the monitor as much as possible, with an almost imperceptible monitor experiencing these preferences through research and feedback. These requirements could provide difficulties for the subsequent stages of Identifying technical requirements for each component. For example, when designing our monitor, we tried to make it as tiny as possible, but the battery size requirement forced us to make the monitor's width equal to the battery's width. Generate multiple design ideas that fulfill user requirements and technical constraints through brainstorming. Evaluate each idea against the established criteria and select the most promising concept from all ideas.

After printing the prototype, iterative design is critical to improving the wPUM design, which was the most extended period of this whole process. Engage in iterative design cycles to refine and improve the prototype based on user feedback and expert input.

The second aim of this work was to articulate a design framework for future designers of topography monitors. This framework is a guideline for focusing on specific components and considerations, using standardized terminology for clarity and consistency. This framework will help future designers target user demands, achieve continuous improvement through iterative design methods, and manage the challenges of designing topographical monitors.

5.2 Recommendation for Future Work

This monitor needs additional in-lab validation testing before it can be deployed in the field and fully commissioned. A few validations have previously been completed; for further details, check MEM0182 and MEM0178 (Dr. Hensel). Since the beginning of this thesis, IQOS designs have undergone numerous additions. To inform future revisions, staying up to date with industry developments, technological improvements, and consumer input is imperative. The IQOS monitor's future designs must be considered further IQOS products. Also, inputs from field studies from lab staff and users can improve the monitor's design and performance.

Designing the monitor with a movable mouthpiece makes sense for user ease and maintenance. A particular material must be used to guarantee that the removable mouthpiece is robust, simple to maintain, and suitable for the heat stick's squishy properties. In addition, make sure the mouthpiece is compatible with various squishy heat sticks of different sizes and shapes commonly used with tobacco products. Consider potential variations in the heat stick's size and texture while creating the mouthpiece. The printed parts can be tested using finite elements analysis to identify their weak points and inform the next design.

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