

THE EFFECT OF COLOR, SYMBOL, TEXT, PACKAGE MORPHOLOGY ON THE
ABILITY OF HEALTHCARE PROFESSIONALS TO DETECT OPENING FEATURES IN
STERILE BARRIER PACKAGING FOR MEDICAL DEVICES

By

Prutha Kedar

A THESIS

Submitted to
Michigan State University
in partial fulfillment of the requirements
for the degree of

Packaging – Master of Science

2024

ABSTRACT

Current trends leverage the idea of “engineering safety into the overall health system to reduce errors and improve health outcomes. Research suggests that healthcare providers often deviate from intended opening practice when opening packaging containing sterile devices, and that this deviation significantly impacts the likelihood that a sterile device will encounter non-sterile surfaces during the transfer process.

We objectively evaluated how different design features (color, symbol, text, shape morphology) impact healthcare providers’ ability to identify where to begin opening using a computer-based task and methods approved as STUDY 00008547. Fifty-six healthcare providers participated in the task, which investigated the use of color, text, symbol and morphology indicating opening feature on the ability to accurately (a binary variable) and quickly (continuous variable) identify the opening location. All features were tested at two levels (present and absent) and all were crossed and presented on three package types commonly used for medical devices (tear pouches, corner peel pouches and tray lids).

The major findings from our study suggested that the presence of design cues on the three types of packages enabled quicker time to correct identification ($p < 0.0001$). The presence of various combinations of design cues also contributed towards enhancing the accuracy of correctly identifying the opening location ($p < 0.0001$). The only morphology trial displayed the lowest accuracy (62%) and longer time to correct response in the three package types. Professional experience of participants did not show significant difference on the accuracy ($p = 0.0514$) or time ($p = 0.9738$) to correct response in participants. Age showed a significant effect on response time ($p = 0.0363$).

Keywords: Aseptic packaging, opening features, engineering safety, Human Factors, usability evaluation.

ACKNOWLEDGEMENTS

This process has been a collective endeavor, harnessing the combined expertise, dedication, and collaboration of everyone involved and I would like to acknowledge all the people that have supported me throughout this journey.

I have been lucky to have Dr. Laura Bix as my research advisor. I received the opportunity to delve deeply into medical packaging and enhance my skills in identifying critical gaps, scientific thinking, and fostering a strong curiosity to study the root cause of any problem. This research experience has evolved me on a professional and personal level, and I am extremely grateful for this opportunity and would like to express my deep gratitude to Dr. Laura Bix. Furthermore, I want to thank my committee members Dr. Mary Kay Smith and Dr. Rafael Auras for their unwavering support throughout my master's journey. Dr. Mary Kay Smith's extensive network and experience with healthcare assessment and teaching facilitated seamless scheduling of participants, your assistance has been crucial for achieving my research goals. Additionally, I am privileged to have Dr. Auras on my committee, a distinguished faculty member in the School of Packaging renowned for his expertise in sustainable packaging. Studying PKG 825: Polymeric Packaging materials under Dr. Auras was an insightful experience which deepened my understanding and passion for packaging.

I am deeply honored and grateful to the Association for the Advancement of Medical Instrumentation (AAMI) for funding this research study and supporting researcher's and professional's efforts towards creating advanced solutions in healthcare technology.

A heartfelt acknowledgement to the healthcare professionals who dedicate themselves tirelessly to delivering exceptional patient care. I appreciate their invaluable time devoted to participating in this study. Their feedback plays a pivotal role in creating functional packaging of medical devices. A majority portion of our data analysis was possible with the support of the Statistical Center of MSU's College of Agricultural Resources. I am extremely grateful to the statisticians who contributed towards the analysis in my study and were always helpful with solving the huge number of concerns and doubts that I had.

Designing the experiment and collecting data from participants was an arduous procedure, but my colleagues in the School of Packaging and HUB research group made it possible to achieve the goals. Thank you Dr. Lanqing Liu, and Krishnaa Venkatesan for assisting me with the coding my experiment in Microsoft visual basic and the e-prime software. Your combined expertise really

helped me design my experiments successfully with zero errors and I am so immensely grateful for that. David Mcfarlane is a systems designer and an expert with E-prime software who helped me validate my E-prime code to ensure there are no errors. Thank you, HUB members and students Rodney Cancler, Brandon Coleman, Alonda Johnson, Samuel Ofosu for helping me with the data collection.

My family is my pillar of support, encouraging me to fearlessly aim higher and work hard towards my goal, thank you for believing in me and having the courage to let me travel to the other side of the globe to pursue my dreams. To my friends who have been a huge part of my journey and were always there for my support, together we have experienced our fair share of challenges and triumphs that have only made us stronger.

This was a combined effort and everyone who was a part of this holds the highest level of love and respect in my heart.

TABLE OF CONTENTS

1. Introduction	1
2. Literature Review	5
3. Research Objectives	11
4. Methodology	12
5. Results	23
6. Conclusion	69
REFERENCES	73
APPENDIX A: APPROVED FORMS AND DOCUMENTS	75
APPENDIX B: TRIAL IMAGE FILES	82
APPENDIX C: INTERACTION BETWEEN TWO DESIGN CUES	95

1. Introduction

Medical device packaging is a crucial contributor towards patient health and can serve to assist or hinder healthcare professionals in intense user environment. Key requirements include enable and maintenance of sterility and safety, preserve and extend the integrity of the products they contain and factors that permit quick and easy useability to the user (Cai, 2012) . A myriad of factors needs to be considered when designing medical device packaging. The package which holds the product and the labeling of the package need to be aligned and communicate precise information to the healthcare providers so that the device can be used aseptically and effectively (Bix et al., 2016) . Medical device packages that possess a very strong seal strength, unusual sizes, unclear opening features have the potential to affect useability and increase difficulty of aseptic presentation (Gosbee & Gosbee, 2011). Studies that examine the relationship between packaging, aseptic presentation, and their potential role in patient outcomes are important to understand how effective the packaging is in the hands of the user. Research suggests that the package size, package design, and user training and techniques all impart significant effects.(Lee et al., 2021a). These parameters bring attention to the significance of human factors and useability evaluation in medical device packaging.

1.1 Aseptic Packaging and Sterile Barrier Systems (SBS)

The important functions of packaging are protection, useability, and communication (Bix & de la Fuente 2010). Protection in medical device packaging focuses on prevention of contamination of the medical device due to any external microbes (Perez, 2018), healthcare professionals need to follow specific procedures to establish and maintain sterile field. This can be explained using “Aseptic Technique” that are set of practices and procedures performed under carefully controlled conditions to minimize contamination of sterile field by pathogens (Narins, 2013). The factors considered while designing a medical device package have significant effect on the aseptic techniques because it involves the way healthcare professionals interpret these packages and use the contents (Cai, 2012)

Another term widely used with aseptic techniques is Sterile Barrier Systems (SBS). ISO 11607-1:2006 introduced the term” Sterile Barrier Systems” to describe the “minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use.” 11607-1:2019, 2024).

1.2 Industry Standards and Regulations

The ISO 11607-1:2019 guides the requirements for materials, sterile barrier systems and packaging systems intended to maintain their sterility until the point of use (11607-1:2019, 2024). The significance of the opening feature or intended use is included under the labelling requirements which comprise of label, instructions for use and any other information that is related to identification, technical description, intended purpose and proper use of health care product. This requires medical device manufacturers to provide useability evaluation, ability to identify the opening feature, perform the technique to open the package without contaminating or damaging the device (11607-1:2019, 2024).

The chapter “Packaging needs for healthcare facility” published by Reichert Consulting in Medical device packaging handbook covers factors in packaging needed by healthcare providers like labelling that enables quick identification, simple illustrated directions of use, package that allows aseptic presentation among others (Sherman, 1998).

The association of peri-operative registered nurses (AORN) and Association of Surgical Technologists (AST) are two organizations that represent clinicians and work towards providing guidelines, documents, and evidence-based practice recommendations for surgical practices (recommended practices, 2012), (Guidelines for Best Practices, 2019) .

The association for the Advancement of Medical Instrumentation (AAMI) is a nonprofit organization that works on the development, management and guidance for healthcare technology and sterilization professionals. These organizations include guidelines on packaging opening, handling, and successful transfer to sterile field without contamination based on traditional practices.

Experiments or case studies that evaluate useability studies are crucial to understanding the relationship between package design and level of contamination risks. To achieve the goal of eliminating contamination in sterile packaging, ANSI (American National Standards Institute)/ AAMI/ ISO 11607 -1:2019 introduced useability evaluation requirement for aseptic presentation of terminally sterilized medical devices (11607-1:2019, 2024), (Qin et al., 2023).

Even as standards and requirements for packaging change to engineer safety into healthcare, there is limited objective evidence to help us understand the relationship of packaging design to provider behaviors, and ultimately, patient outcomes, the reason being that these errors associated with packaging and labeling tend to remain underlined and the mistake occurs before the problem is

visible (i.e. contamination that results due to improper transfer of device may lead to a potential infection) (Lee et al., 2021a). The influence of package designs on the ability of the healthcare provider (or patient) to accomplish critical tasks (e.g., properly identifying, aseptically opening, and transferring, and properly dosing and administering) is not researched enough. Only in recent times have the regulatory bodies identified this gap and worked on creating standards and regulations which call for the objective evaluation of the ability of packaging to facilitate appropriate performance when handled by users (Lee et al., 2021b)

1.3 Relationship between packaging of medical device and Healthcare Acquired Infections (HAIs)

Healthcare associated infections are unanticipated infections that develop during healthcare trial and can result in significant patient illness (Perez, 2018). The transmission of HAIs can take place directly; from a person to patient or indirectly through an intermediate object i.e. medical device. In one such study by Gastmeier et al, it was noted that out of 1,022 outbreaks related to HAIs, 12% were associated with medical device (Gastmeier et al., 2005).

Although the relationship between package design and the techniques employed by healthcare providers during sterile transfer and healthcare associated infections (HAIs) has yet to be thoroughly characterized, it is not unreasonable to assume that a device touching a non-sterile surface during aseptic transfer is an undesirable result which could serve as a potential vector for HAIs, a noted problem in healthcare (Lee et al., 2021a).

Given the important role that packaging plays in ensuring sterility (all the way to the point of delivery to the patient), and intensive situations present in healthcare environments, ease of use is of paramount importance. Packages containing sterile devices must be designed so that actions can be quickly and accurately completed in ways that facilitate the device transfer cleanly.

Current trends leverage the idea of “engineering safety into the overall health system” to reduce errors and improve health outcomes. These trends are augmenting how we design and evaluate medical packaging, and are reflected in the introduction of, and changes to, regulations.

(Perez, 2018).

1.4 Design and Human Factors

The relationship between different design features and their ability to enable aseptic presentation is not widely studied (Trier et al., n.d.). Design is a communication method that, ideally, indicates to the user how to use a product- through the product itself (Andersen et al., 2021).

There are three design principles related to the perception of information that are critical for creating simple, usable package designs: the principle of visibility, 1) signal-to-noise ratio 2) and 3) recognition over-recall advantage. According to the principle of visibility, the usability of a product or system improves, when possible, actions (e.g., lift tab), and the subsequent result of the actions (e.g. to open), are clearly indicated by the design (Lidwell et al., 2010). Click or tap here to enter text. The measure of success of a packaging design can be identified by the extent to which the action intended for the product is also the action most afforded by the item (de la Fuente et al., 2016). Packaging engineers can thus measure the level of affordability by performing real life user studies. This process emphasizes a user-centered design approach (UCD), rather than a product-centered design approach (PCD) (Keates & Clarkson, 2004).

These factors, when incorporated while the designing of medical device packages, possess the ability to be used correctly, without any confusion, error or contamination that is caused to the user, in this context a healthcare provider.

The goal of this study is to study how the presence of color, symbol, text morphology, will have a significant influence on identifying the opening tab and whether the participants maintain sterile technique throughout the opening process.

2. Literature Review

It has long been suggested that the design of packaging for medical devices should encourage appropriate opening of these products. Reichert's chapter on "Packaging needs for the health Care-Facility" in the Medical Device Packaging Handbook (Sherman,1998) indicates that the opening instructions of healthcare packaging should be easily understood by the healthcare personnel and consider the intense working environment. Designs must consider an end user with no previous experience with the product (Sherman,1998) and should be validated by simulating the environment where interactions take place.

An article by Butschli on a two-day event on Healthcare Packaging Immersion Experience at Michigan State University provided a platform to acknowledge and understand the gaps in medical device useability in an operation room or emergency room and how packaging plays a role in this. Michigan State University's School of Packaging, College of Human Medicine, Osteopathic Medicine, Nursing and Veterinary Medicine teamed up with Oliver-Tolas Healthcare Packaging to conduct two-day event at the Learning and Assessment Center (LAC) to examine how medical device packages operate in Emergency rooms and Operating rooms (Butschli, 2011). The participants experienced simulated surgery and an emergency room event to identify the gaps in the package handling of a medical device and sterile presentation. Dr. Mary Kay Smith emphasized how such simulations provide an opportunity to evaluate the gaps in device and package handling. Some key insights from the two-day event suggest that nurses encounter packaging issues in 1 out of every 5 procedures. Furthermore, issues with presenting the product within a sterile field generally lead to disposing of the device, leading to wastage (Butschli, 2011).

Despite these urgings, there are a limited number of studies that investigate the interface between providers and medical devices, and even fewer focus specifically on how design influences opening feature and the ability to aseptically transfer a device.

Based on a feedback study with OR personnel, the Duet company developed a pouch design called a "chevron header pouch" that combines the elements from header bag and chevron pouch. The OR personnel were organized into different focus groups to receive insights regarding the packaging of medical devices. A persistent complaint of the focus groups suggested that healthcare providers faced difficulty in interpreting or understanding the opening features in a medical device package. The structural indicators in medical device packages did not contribute to intuitive opening which led to a serious concern that incorrectly opening a package may compromise the

sterility of the contents. The goal of a chevron header pouch was to improve pouch access and aseptic presentation (Operating room personnel input critical to new peelable Chevron header pouch 2017).

Cai's work focused on investigating the medical packaging needs of operating room personnel by identifying common problems associated with medical device packaging (Cai, 2012).

Data from seven focus groups were organized consisting of 21 operating room healthcare personnel in greater Lansing and Cleveland areas was analyzed by organizing focus groups data into qualitative thought units based on frequency, and relation with packaging design. The various packaging factors were ranked by their level of importance. The thought units (N= 1095) which can be linked to this research merged around the concept of a) opening and aseptic presentation b) quick identification among others. The findings suggested 49.7% of the total thought units categorized as opening and aseptic presentation and 16.4% of recorded units focused on the identification of contents. The participants also ranked grip space, preopening integrity, seal/peel strength and easy to read label as most important factors in medical device packaging. Even though the top 10 ranked features rated packaging integrity before opening the highest, followed by easy-to-read text/font labeling, the list also included concerned opening and aseptic presentation and quick opening among their top 10 ranked features.

Cai's findings also suggested that labeling plays an important role in conveying important information and is among the first points of interaction with most products (Cai, 2012). Consideration of human factors within the context of the surrounding environment is a fundamental step in the design process of medical device packaging.

Lee's work provided insights on problems associated with packaging design in pre-hospital settings and investigated the various coping strategies paramedics resort to when difficulties occurred in the packaging. Emergency Medical services are administered during prehospital care to stabilize patients and transport them to a hospital better equipped to provide comprehensive care. Poor lighting, extreme heat or cold, noise, chaos, vibration due to vehicle movement, interloping friends and family are just few of the extreme conditions among others that are present in an emergency vehicle which are not very well considered during product package designing(Lee et al., 2021b) One of the most common errors that contribute to transport related adverse events was identified by Bergman et al and they are associated with the category "tools and technology" and within this category a common problem was products that were not designed in ways that

consider the context/environment of care and support the needs of healthcare providers (Bergman et al., 2017) It was observed that paramedics resorted to flashlights to identify products or use one hand and scissors, teeth to open items required urgently(Lee et al., 2021b).

One study tried to evaluate how the label information on a medical device package is processed and whether various design elements affect this information processing in a positive way. Bix et al conducted studies to investigate the efficacy of boxing, grouping, symbol presence and color-coding to critical information, during most stages of information processing (Bix et al., 2016).

Medical device labels are the first form of interaction between the device and the healthcare provider, hence they play a key role in enhancing information processing and ensure that the device is used safely and effectively (Bix et al., 2016). Two of the three experimental parts of this study aligns with our approach of study; a) a study investigating how design strategies impact early stages of information processing using change detection method, also evaluating symbol comprehension b) a forced choice task that enumerates the effect of design elements on the correct selection of device and time to select the same. These design factors were also compared with 2 commercial medical device labels to identify the efficacy. Four design factors were evaluated: grouping of critical information, boxing of critical information, symbol presence/absence and color coding. 189 perioperative personnel participated in this study. It was noted that participants detected changes faster when three pieces of critical information were boxed than when they were unboxed in grouped and ($p=0.0086$) ungrouped ($p<0.0001$) formats. 3-way interaction term of boxing x symbol x color was significant ($p=0.0323$). Even though grouping enhanced the performance in trails with colors, the performance evidently slowed down in boxed conditions. During symbol evaluation 6 out of 38 symbols in the internationally recognized standard were considered “critically confusing” for participants. They were also interpreted to convey the opposite meaning than the intended task.

The three design effects color, grouping, symbol decreased time to selection when the participants were asked to identify a product with a specific feature. The presence of symbols and color coding, grouping of information showed less time to select correct device in comparison to the commercial labels.

Bix et al was able to provide evidence that medical device manufacturers need to employ design elements to develop a standard labeling format for critical information (Bix et al., 2016). The linkage between package design and its impact on sterile transfer of medical devices was evaluated

by Paula Perez. 136 healthcare providers were asked to present medical devices to a simulated sterile field. The aim of this research was to evaluate package designs like inward curl, outward curl, tab design and commercial pouch designs' likelihood of contaminating the device i.e contacting non-sterile surface and characterize how aseptic technique affects the probability of contact between medical devices and non-sterile surfaces during sterile transfer. Participant's gloves and outer side of the test pouches were coated with contamination simulant. The participants were asked to present the content of various pouch designs using two transfer techniques: standard technique and modified technique. Standard technique followed typical approach for presentation and modified technique required participants to grab the package at the top center and transfer contents to the field using a single fluid motion. It was observed that pouches with outward curl resulted in less contact than all other designs for both standard and modern techniques. standard technique: (outward vs. commercial, inward and tab pouch) ($14\pm 2.5\%$ vs. $26\pm 3.5\%$ ($P < 0.0047$), $25\pm 3.4\%$ ($P < 0.0140$) and $23\pm 3.3\%$ ($P < 0.0418$), respectively) and modified technique (outward vs. commercial, inward and tab pouch) ($8\pm 1.8\%$ vs. $22\pm 3.2\%$, $25\pm 3.5\%$ and $25\pm 3.5\%$ respectively; all comparisons $P = < 0.0001$).

2.1 The theory of Affordance

The concept of affordance was proposed by J.J Gibson on the premise: the form of objects around us shapes a perception of what is possible to do with them (Gibson, 2014). This means, as much as the user interacts or uses the product, the product itself guides the user on how to interpret it and use it. The idea that physical objects in the environment have functional meaning to an observer revolutionized the field of visual perception (de la Fuente et al., 2016).

Norman, a cognitive psychologist identified that Gibson's concept of affordance is applied in design practices, some of the examples include push-bar door opening mechanism which affords or signals the user to press the door to open it. (Norman, n.d.). Norman applied this theory to explain user-product interaction by introducing "perceived affordances". Perceived affordances can be defined as design features or cues which communicate how to interpret a product or its use. Norman suggested that affordances are in simple terms "signals" that communicate what action the user can perform with the product (Norman, n.d.).

Javier de la Fuente adapted this theory of affordance to improve the usability of packaging designs. He conducted an experiment to develop a methodology to evaluate package designs considering users, context of use, task and design features. Their case study consisted of a folding carton with

a syringe and vial which is used in situations where time is critical and sometimes chaotic, typically an emergency room or operating room and ambulances. two types of carton designs were tested; one using the original carton and second being a redesign that incorporated changes like rotation of front panel text to guide users to hold the right orientation, addition of a folding tab on the side to guide folding and tearing, minimization of visible edges and corners on the bottom end to avoid inappropriate opening. While designing any kind of package for a product, the way it interacts with the user is crucial, because that decides whether the package is successful or not. Human-
Package interaction consists of several steps that should be established to ensure successful useability. An ideal package design communicates immediate understanding of use, opening (where and how), proper and accurate dispensing, reclosure and disposal (de la Fuente et al., 2016). 26 participants were recruited at the learning and assessment centers at Michigan State University. The participants were required to stand behind a counter of a fixed height of 110 cm and needed to complete two opening tasks in healthcare facility. The participants were asked to picture an emergency where they had to quickly take out two wooden dowels from packages that were under the dust covers. Time started recording when “go” signal and stopped when both the dowels were taken out. The opening time tells us the time needed by the participants to grasp the package, open it and handle its contents (de la Fuente et al., 2016). The order of the presentation was balanced across designs. By contrast, the results regarding the redesigned package suggested that the design changes (text oriented intuitively to opening mechanism, a cultural constraint), and the added tear tab, a physical constraint, resulted in stronger signal strength regarding the intended affordances (de la Fuente et al., 2016). All 26 participants started opening the package at the end that was intended (the top). None of the participants switched ends during opening (or opened both ends), and just a single package was torn to the point that text was damaged.

Quick and appropriate opening can help ensure aseptic presentation, important in a variety of healthcare settings. Through this, we propose to evaluate and create evidence on how healthcare professionals perform when searching for information on a medical device package label used in hospital settings using design perception theories.

Human Factors Engineering

Human factors engineering (HFE) can be described as studying and applying human capabilities (physical, sensory, emotional, intellectual) and human limitations for developing devices, systems, mechanisms. HFE combines the use of behavioral science and engineering methodologies to create effective designs (Hegde, 2013).

The benefits of implementing HFE in medical device packaging is reduction in packaging related errors like aseptic presentation due to incorrect opening, ease of use, reducing the time to identify the functions of a package and user satisfaction. This sheds light on the significance of user perspective while designing medical device packages. It is crucial for manufacturers to identify the environment the package is going to be used in, the kind of user operating the package and flexibility and limitations the user is going to face in that environment. Misunderstanding between package design and functionality can lead to errors which have minimum tolerance in a hospital setting.

3. Research Objective

Research suggests that healthcare providers often deviate from intended opening practice when opening packaging containing sterile devices, and that this deviation significantly impacts the likelihood that a sterile device will encounter non-sterile surfaces during the transfer process (Perez, 2018).

To test the efficacy of varied design strategy's ability to attract the attention of healthcare providers to the intended opening feature, a computer-based task was conducted with 56 healthcare providers. The experiment not only provides objective evaluation of how varying design cues impact healthcare providers' ability to identify the opening feature on packages containing sterile medical devices, but also proposes and tests a method that can be used to evaluate how effective other design features are at garnering attention.

We hypothesize that distinctive techniques, such as the use of color, the presence of a symbol, or changing a package's shape have the potential to reduce the time it takes healthcare providers to identify the proper place to initiate the opening task for sterile packaging.

4. Methodology

The experiment was conducted in room 159 HUB laboratory, School of Packaging, Michigan State University. The experiment was reviewed by the MSU Human Research Protection Program HRPP- part of MSU's Office of Regulatory Affairs under # STUDY00008547 IRB and was determined as exempt 3(i)b. Procedures utilized follow those proposed in our IRB application.

A total of 56 participants were recruited utilizing local healthcare networks available to collaborator Dr. Mary Kay Smith, Director of the Learning and Assessment Center (LAC) at Michigan State University and Dr. Larissa Miller, an NLN Certified Nurse Educator and an ANCC Board Certified Professional Development Specialist serving as the Coordinator of Professional Education for the College of Nursing at MSU. Further recruitment involved distribution of IRB approved fliers (see Appendix A) to test participants. The number of participants (56) were computed with the help of College of Agriculture and Natural Resources statistical counseling center using power calculations for the total number of trails (package type x permutation and combination of design cues x location of design cues) at 85% confidence level. Ultimately, data was collected from 56 participants who were divided between 4 program sets, categorizing 14 participants in each program set that balanced designs across opening location (See Figure 4.9– with more details to follow).

Inclusion criteria for participation required subjects to:

- Be 18 years or older.
- Be currently working or have history of employment as a healthcare professional involved in aseptic technique and have experience in aseptic presentation, or
- Currently be a student enrolled in a healthcare program that has completed training in aseptic presentation with practical experience in aseptic technique as a part of your healthcare program.

Participants called or emailed to schedule a mutually convenient time for testing, during which they were screened using the eligibility criteria. The participant schedule was tracked using Microsoft excel sheet to note down their contact information, appointment date and time so that a reminder call could be placed 24 hours in advance of testing. Participants that required parking were provided with a 2-hour parking pass.

Upon arrival at the lab, an approved, written consent was provided (see Appendix A) along with a brief explanation of the experiment, including the time it would take, and the compensation

provided. Participants were told that they could opt out of any part of the testing or discontinue altogether without penalty. Upon providing written, informed consent, they were provided with a sheet to fill in their demographic information followed by conducting visual acuity pretests, whose results were noted down in the same sheet.

Funding provided from an Association for the Advancement of Medical Instrumentation (AAMI) Kilmer Grant enabled provision of \$50 to compensate each subject for participation. Data was recorded by the participant number, with no link to their identity and stored in the HUB lab.

4.1 Demographic Information and Pretest

The first portion of the research was comprised of a survey (See Appendix A) and simple pre-tests intended to characterize the participants. Basic demographic details such as age, sex assigned at birth, and information related to their work history (e.g. profession, number of years in this profession) were collected, followed by a series of pretests.

The pretest consisted of two tests:

I. Near point visual acuity

In accordance with methods described by the test manufacturer, Precision Vision (Woodstock, Illinois), participants were instructed to hold a vision card (See figure 4.1) 16 inches away from their eyes and read the lowest line on the card visible to them without excessive strain. The lowest line they could read comfortably correctly was noted and the score corresponding to that line was recorded (ranging from 20/20 to 20/800) in accordance with test directives.

II. Color Vision Test

To test color vision, a set of H.R.R pseudoisochromatic plates (Elgin, Illinois) were used to investigate and record the participants ability to perceive and differentiate color. This was a very basic level screening test to ensure participants do not encounter issues when viewing colors on the screen. (See figure 4.1).

The participants were instructed to read the number present on 6 color plates provided to them. The participants were asked to answer 3 specific questions: 1) how many symbols do you see? 2) Identify the shape of the symbol 3) which quadrant they are present in (point out the exact location of the symbol). Their responses were recorded in binary fashion as correct/incorrect. The ability to respond to all three questions accurately was marked as correct; However, any single wrong answer among the trio was deemed as an overall incorrect response. The ability to correctly answer the three questions of the 6 plates suggests normal color-vision. One or more errors need another

round of testing the same six plates. Since this was a preliminary test to ensure the participants could differentiate color, only one screening round was conducted and results were recorded.

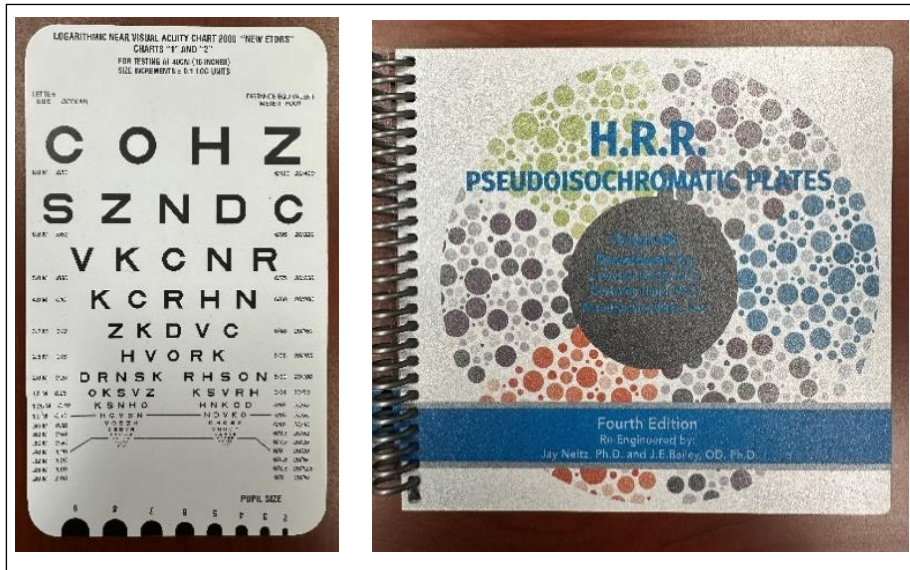


Figure 4.1: Visual acuity card and HRR pseudoisochromatic plates.

4.2 Materials

The HUB lab consisted of 3 workstations for experiments. Hence, at any given time, 3 participants could simultaneously perform the experiments on their respective workstation. The Experimental workstations consisted of a Dell Latitude 5490 laptop with intel i5 processor and Microsoft Windows 10Pro outfitted with a secondary Dell screen (24" x 12") which ran a program code developed in E-Prime Software (V3 for Windows® 11 Pittsburgh, PA USA). The workstation was also equipped with a number pad sourced from Amazon.com (Manufacturer name: Foloda, manufacturer location: China) so that participants could easily and quickly input the appropriate location of opening feature corresponding to the stimulus displayed on the screen (specific information to follow).



Figure 4.2: Number pad used for participant response input.

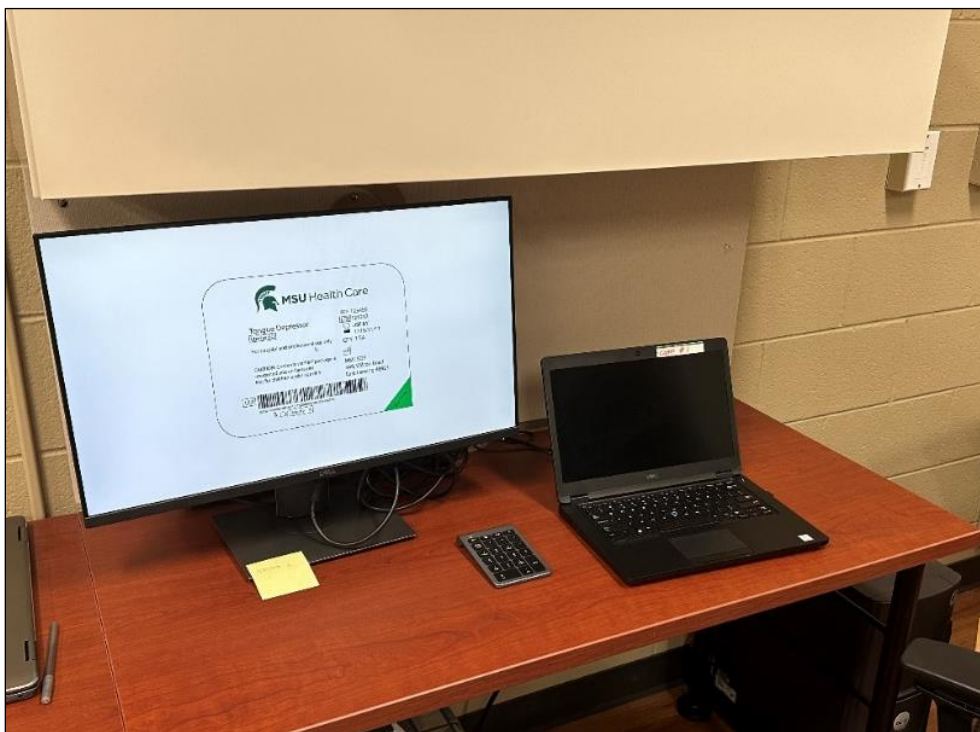


Figure 4.3: workstation with Dell laptop, secondary screen, and a number pad.

4.3 Package Type, Design Cues, Locations

Each of the four-program set consisted of a total of 48 unique trails. These trails comprised of one of three packages commonly used to hold sterile devices (a lidded tray, a peel pouch or a tear pouch) was presented. The package designs were created using Adobe Illustrator CS 3.0 (Adobe

Systems, San Jose, CA) (The size of label for a thermoformed tray selected was 6.6” x 5.1”. For tear pouch and peel pouch, the size selected was 4”x9”.

Four broad design cues were considered, with each presented at two levels (present and absent). The design cues: color, symbol, morphology, and text were utilized to evaluate their effect on enabling the quick and accurate identification of the opening feature across package types. The figures representing the design cues below have been minimized for illustration purposes and do not represent the actual size used in the study.

4.3.1 Color



Figure 4.4: Peel pouch, tear pouch, tray pouch with color design cue.

Color coding is not highly standardized in the medical packaging industry and hence causes confusion with its interpretation (Cai, 2012). Bix et al collected suggestions from participants regarding the resolution of labeling problems, the suggested recommendations from this study included color coding, clear color contrast, highlighted critical information (Bix et al., 2016). Due to the lack of standardization of color in medical device packages, it may have different interpretations for every individual, organization, or culture. Green was selected for the color parameter for its association with green light that indicates “go” or “proceed” and placed on the opening corner/side of the package.

4.3.2 Symbol

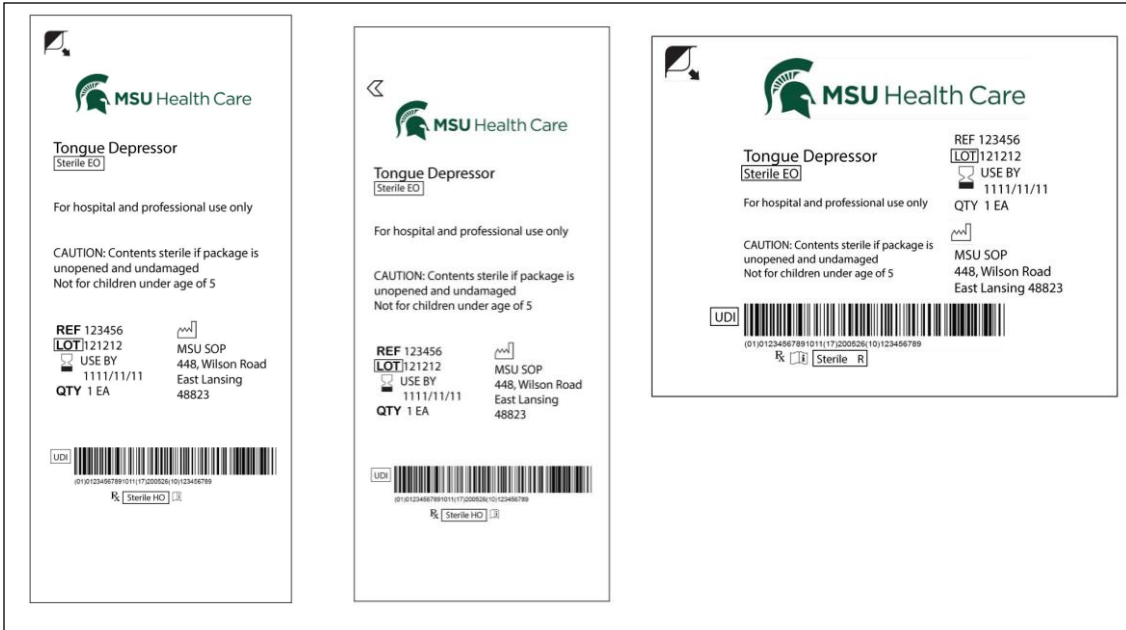


Figure 4.5: Peel pouch, tear pouch, thermoformed tray pouch with symbol design cue.

The “peel here” symbol used in the trails is a standard ISO 7000 graphic symbol to identify the location where the package can be opened and to indicate a method for opening it (7000, 2011). The “peel here” symbol was used for the thermoform tray and peel pouches. The symbol for tear pouch was a simple line to indicate the direction of tear.

4.3.3 Text

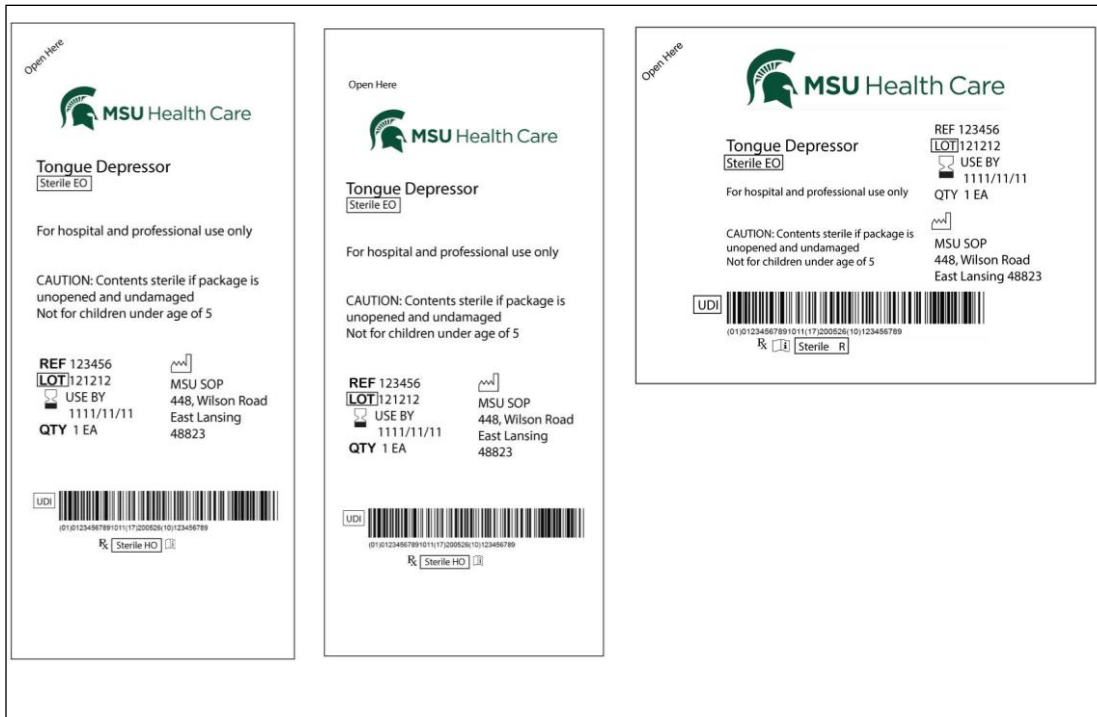


Figure 4.6: Peel pouch, tear pouch, tray pouch with text design cue.

The text “Open here” was used to indicate, in English, the corner where the opening feature was located.

4.3.4 Morphology



Figure 4.7: Peel pouch, tear pouch, tray pouch with morphology design cue.

The shape morphology used were rounded corners for the non-opening corner/side and a sharp corner and a notch (for tear pouch only) for the opening side.

4.4 Design cues

The four factors were tested at two levels namely: morphology (shape modified to indicate feature present and absent); color (present and absent) text (terminology “open here” (present and absent) and symbol (present and absent). All factors were crossed (2 x 2 x 2 x 2) for a total of 16 trails per package (tray, peel pouch and tear pouch) (refer figure 4.8) or 48 stimuli per participant (16 trails x 3 package type). Each combination was created so that each package had each trial combination in each of the four corners. Fifteen of the 16 possible trails were visually expressed (one trial was absence of any of the four design features). As such, the absent trial was not expressed in any of the four locations. All the trails were exported as jpeg images using a visual basic code that converted the illustrator files to .jpeg files achieving all trial combinations for each of the three packages with all possible locations. The size of peel pouch and tear pouch was 4” x 9” and 6.6” x 5.1” for thermoformed tray package. The resolution of the .jpeg files of the three package types was 96 dpi. To calculate the total number of trails required, the total number of design trails expressed visually (15), was multiplied by the total number of locations that a feature could be expressed in (4) by the total number of package types (3); 3 additional trails (no visual expression of opening feature on each of the three package types) meant that a total of 183 stimulus were required (see Figure 4.9).

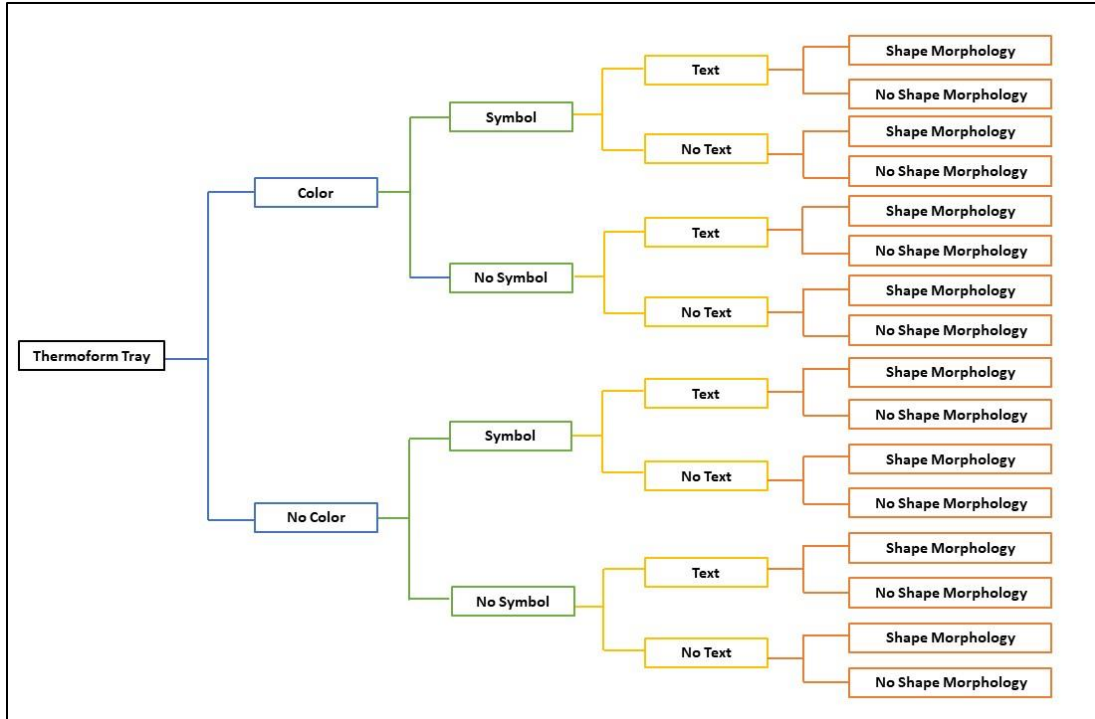


Figure 4.8: The 4 factors tested on 2 levels and crossed with each other to create 16 unique trails for each package type; the above figure is an example for thermoform tray.

4.5 Categorization of all trails into program sets

A set of 4 e-prime programs was created to ensure controlled randomization of the stimuli; these programs were referred to as set 1, set 2, set 3, set 4. Each program consisted of 48 stimuli: 16 from tear pouch, 16 from thermoformed tray, 16 from peel pouch. For any given trial combination (e.g. no color; symbol present, with text and no change in morphology) a given set/program had that feature for a particular package type in only 1 out of the 4 locations. The combination of a given trial and the location of its appearance within a single package type were unique (not repeated) within the 4 sets, thus creating a balanced set. The order of presentation of the 48 stimulus presented in each set was randomized to minimize any run order effects. Participant 1 conducted their study with set one, participant 2 set two and so on. Therefore, a set of four participants represented a complete block where all features were present in all locations. Fifty-six participants were recruited, resulting in a total of 14 complete blocks from the output acquired from the four programs (refer figure 4.9).

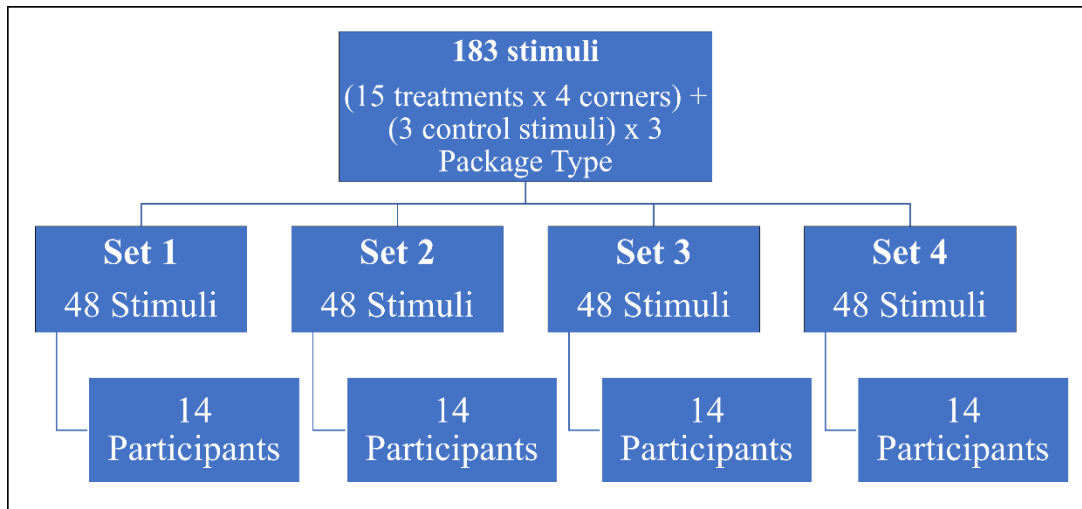


Figure 4.9: Equal division of the stimuli into 4 program sets and number of participants allotted to each program set.

4.6 Procedure

Testing began with inputting the pretest data of the participant into the program. The next slide consisted of an instruction sheet that explained how to perform this experiment, along with the researcher verbally explaining the experiment. This was followed by a practice session to ensure the participants understood the nature of the experiment, and had the opportunity to seek clarification related to any questions that they had.

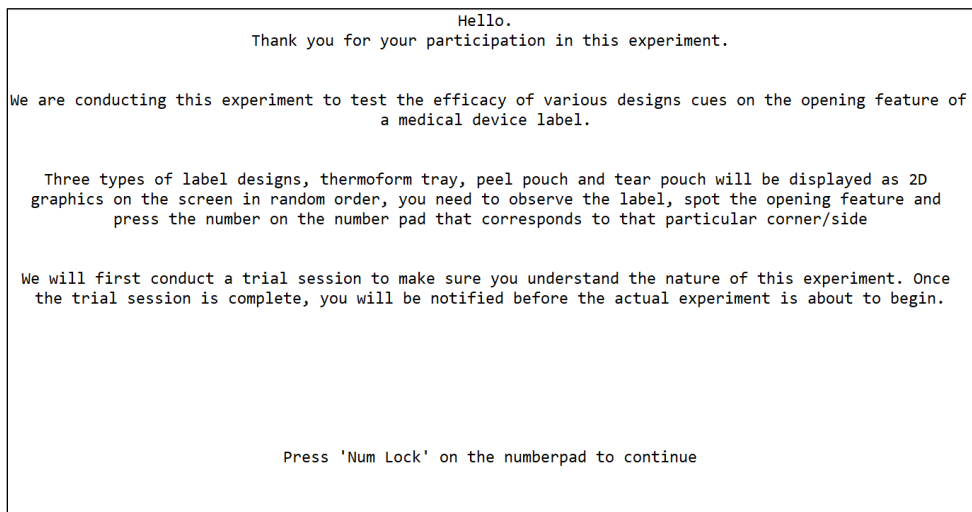


Figure 4.10: Instruction sheet in the program.

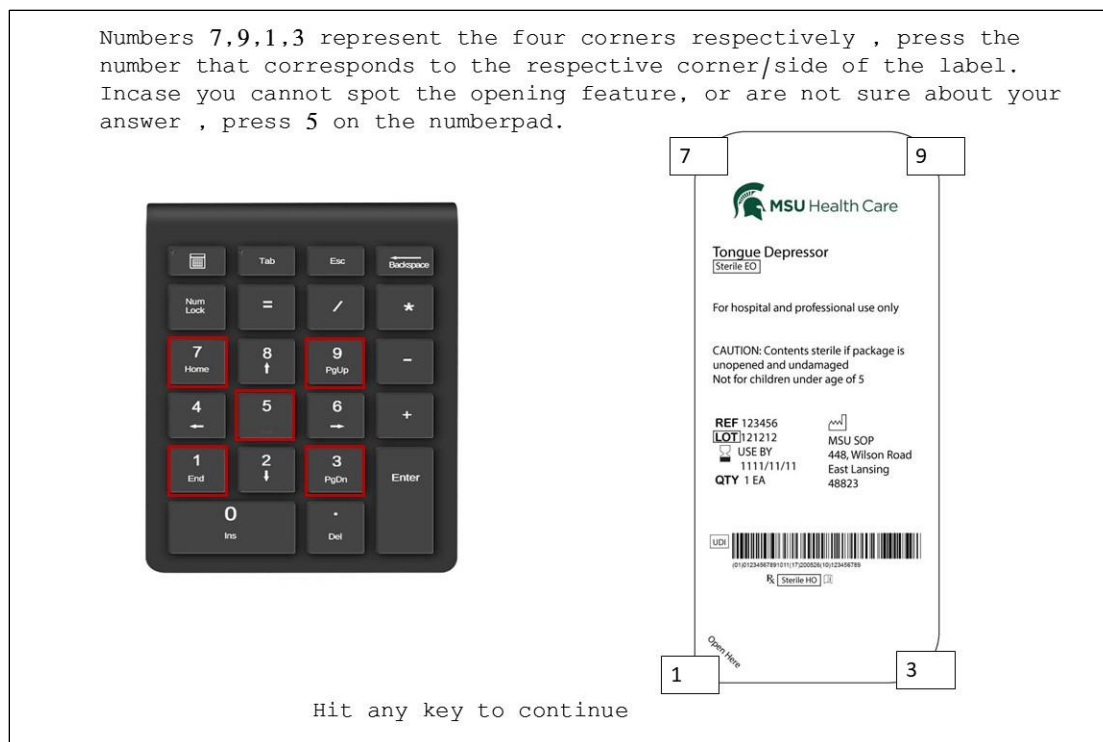


Figure 4.11: Instruction sheet on how to use the number pad for the experiment.

During each experiment, a label (a trial, stimulus image) would appear on the computer screen. The participants needed to observe the label, quickly identify the corner which contained the opening feature and press a number on the number pad that represented that specific corner (See Figure 4.11). Participants were instructed to depress 7 for the upper left-hand corner, 9 for the upper right, 1 for the lower left-hand corner and 3 for the lower right. If the presence of an opening feature was not apparent to the participants, they were asked to indicate the center of the keypad (#5). The next trial appeared on the screen only after the participant response from the previous trial was recorded, creating a gap of 0.5 seconds between each trial. Once the participant completed all 48 trials, the program prompted the experiment to be completed and the data was recorded. Two response variables were measured in this experiment: (1) the ability to accurately identify the opening feature (a binary variable- accurately identified yes/no) and (2) the time to correct identification (a continuous variable).

5. Results

Fourteen complete sets of all combinations of design, presented in all possible locations, were collected using the four programs with 56 participants.

5.1 Population Characteristics

Fifty-six healthcare providers participated in this research. Average participant age was 43.6 years (standard deviation \pm 13.3 years). The population was experienced with aseptic presentation, reporting an average 16.7 years of experience with this practice (standard deviation \pm 12.38 years). The majority of the population reported their occupation as registered nurse (n =37) working in varied environments, including: emergency departments, ICUs, or anesthesia; this was followed by surgical technologists (n= 8), surgical first assistants (n=3), veterinarians (n=3), simulation educators (n=3), a nursing student (n=1), and a physical therapist (n=1). The simulation educators had previously worked as registered nurses. See Figure 8 which depicts frequency by occupation.

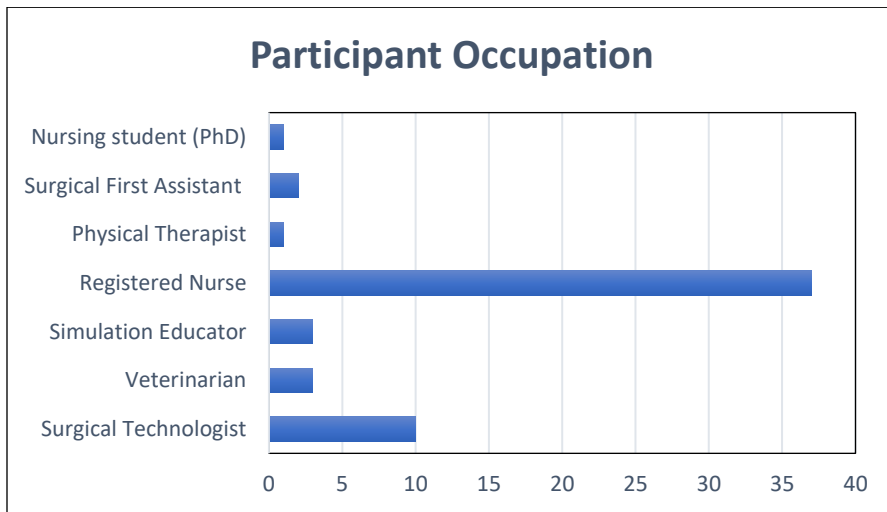


Figure 5.1: Participants' professions in healthcare.

Majority of the population were female. The ratio of female to male population was 45:11 and is depicted in Figure 5.2.

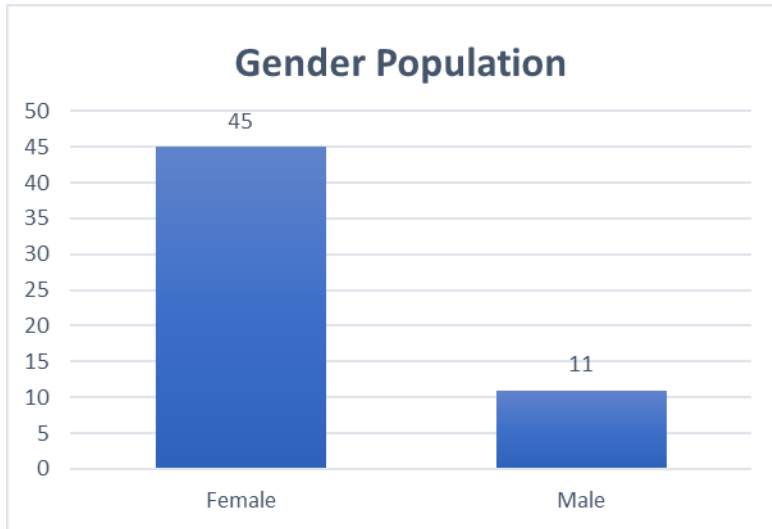


Figure 5.2: Participant gender ratio.

5.1.1 Visual Acuity

Study participants were also characterized by their near point visual acuity. The frequency of results relating to this pretest is presented in Figure 5.3.

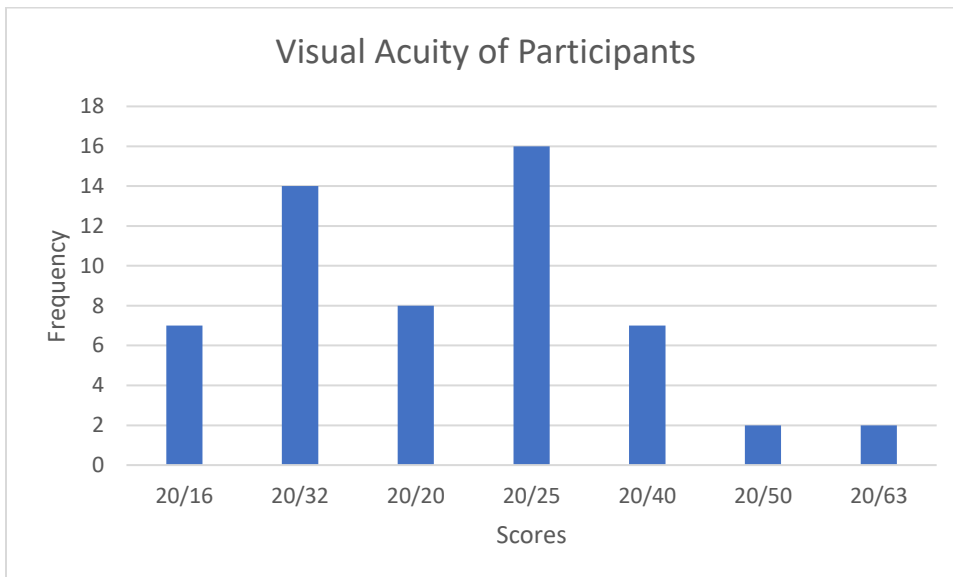


Figure 5.3: Visual acuity of participants.

5.1.2 Color vision data of participants

86% of the participants (48/56) participants were indicated as having normal color vision.

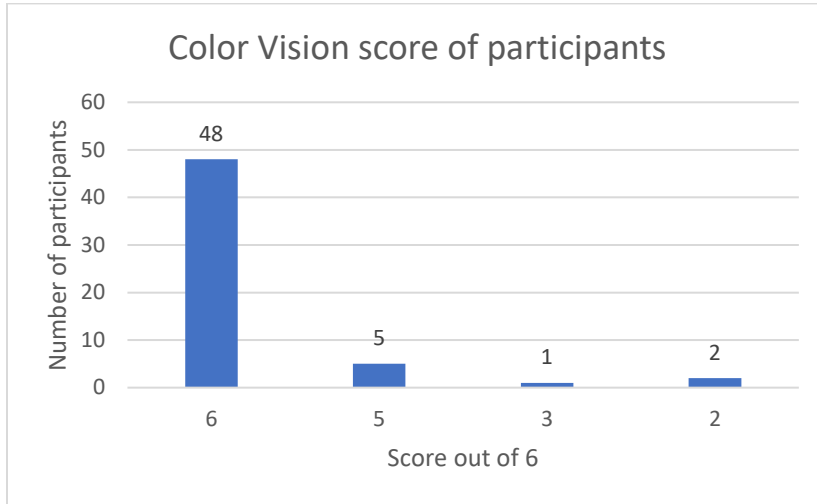


Figure 5.4: Color vision score of participants using pseudoisochromatic plates on a score out of 6.

5.2 Accuracy of responses

The total number of trials were 2,688 (56 participants x 48 trials) out of which 2,613 trials were correctly identified (97%); 2.7% (n= 75) had their location misidentified.

Figure 5.4 provides the participant frequencies by total correct score (0-48). For instance, it can be seen from Figure 5.5 that 21 participants did not miss a single trial, or 37.5% of the participants chose the correct corners for all 48 stimuli presented to them.

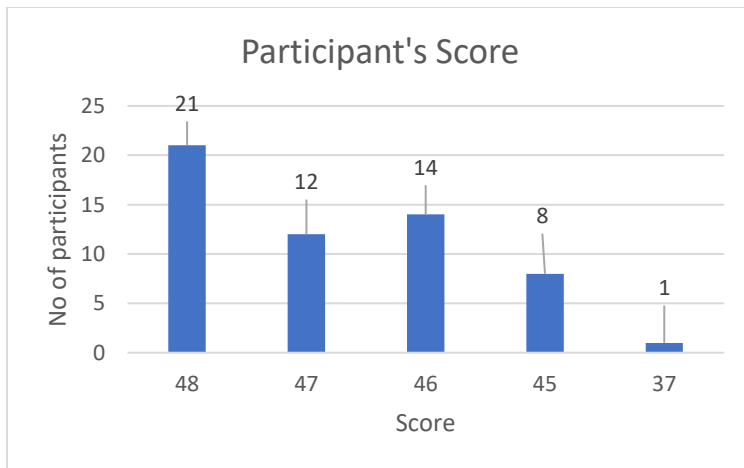


Figure 5.5: Frequency of participants by correct # of trials (out of a possible 48 trials).

We further explored this data statistically to investigate the potential relationship between age and accuracy. The scatterplot age v/s accuracy (Refer figure 5.6) displays the relationship between the accuracy and age, suggesting accuracy was independent of participant age.

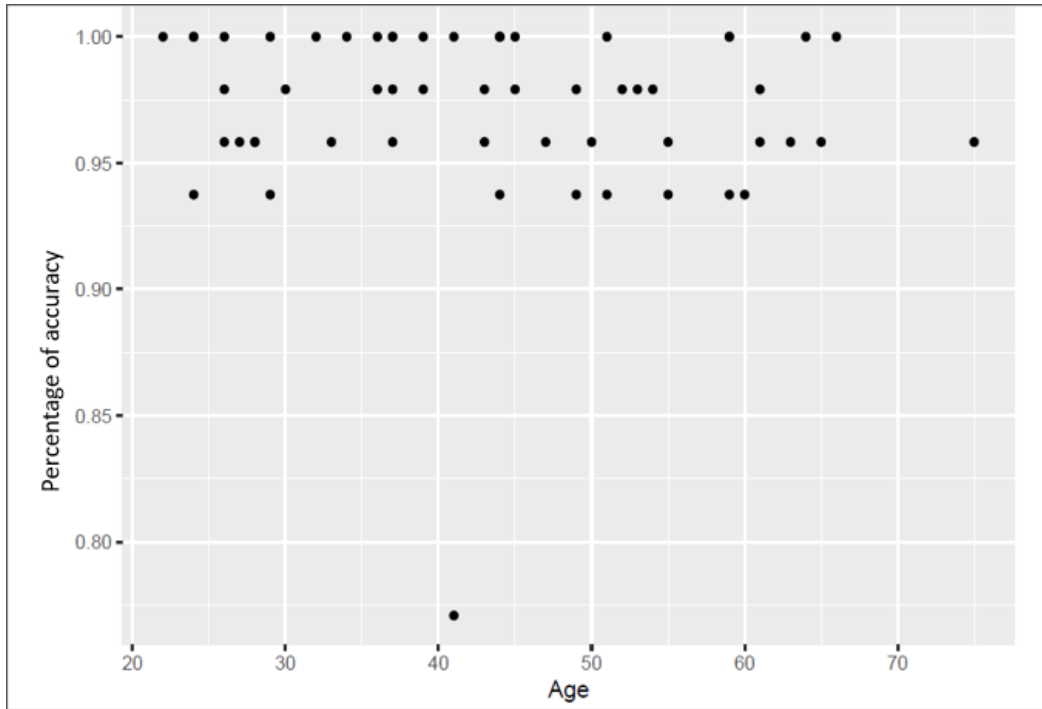


Figure 5.6: Scatterplot describing the relation between age and percentage of accurate response.

The average age of the participant pool that contributed to a given score was also calculated; data is presented in figure 5.7. From both files, there is a single anomaly, with one participant having a score of 37/48 who was age 53. Although the average age of participants increased with decreasing accuracy, no evidence of statistical difference ($p > 0.05$) was found when accuracy results were tested for an effect of age.

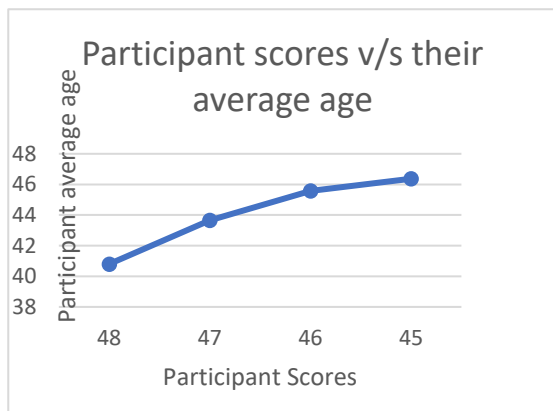


Figure 5.7: Relationship between the scores of participants and their average age.

The data from participants' professional experience (in years) was also statistically analyzed to investigate potential correlation between the accuracy of responses and participant's numbers of

years of professional experience (Refer figure 5.8). The scatterplot in figure 5.8 suggests that the participants' professional experience did not affect their accuracy.

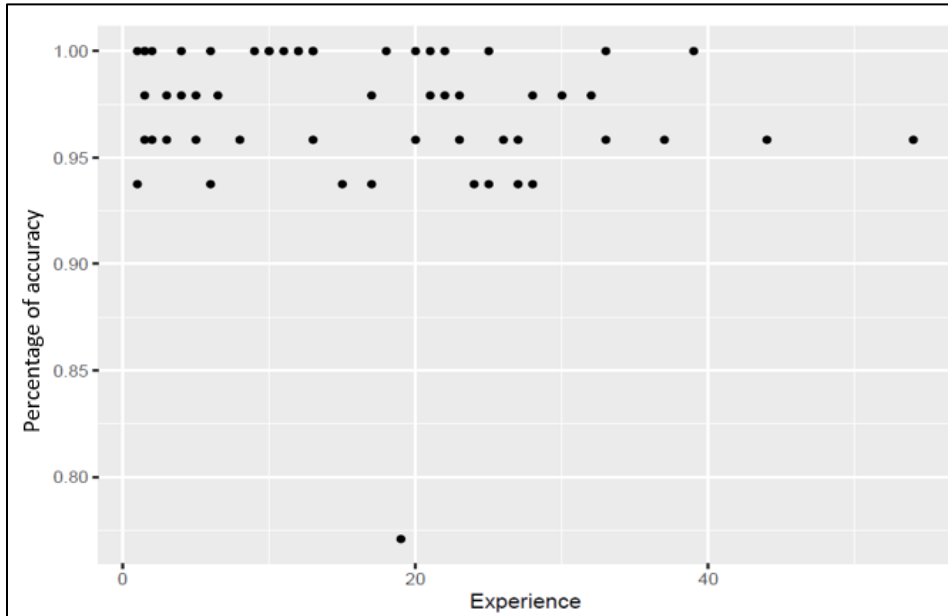


Figure 5.8: Scatterplot describing the relation between participant's professional experience and response accuracy in percentage.

Two different dependent variables were assessed to investigate the data for possible effects: the proportion of correct responses and the time to realize a correct response. Analysis began with the binary variable (opening features correctly identified yes/no).

5.2.1 Trial with lowest accuracy

Figure 5.9 provides an overview of how the different design cues impacted participants ability to correctly identify the opening feature (collapsed across package type and location of feature). As indicated in Figure 5.9, pairwise comparisons suggested no evidence of difference when accuracy rates were compared for all trails but morphology only, which had a significantly lower accuracy rate than all other design cues.

Table 5.1 provides the Least Square Means (LSM) values associated with the probability of correct identification of each of the 16 design trails and significance levels associated with all possible comparisons generated using linear regression model on log odds ratio scale at $\alpha=0.05$. Across all package types and opening locations, the trails with only morphology were correctly identified only 62 % of the total times they were displayed to the participant. This is significantly less than

the accuracy observed for other design cues ($p < 0.0001$) (p values for all pairwise comparisons are located in table 5.1).

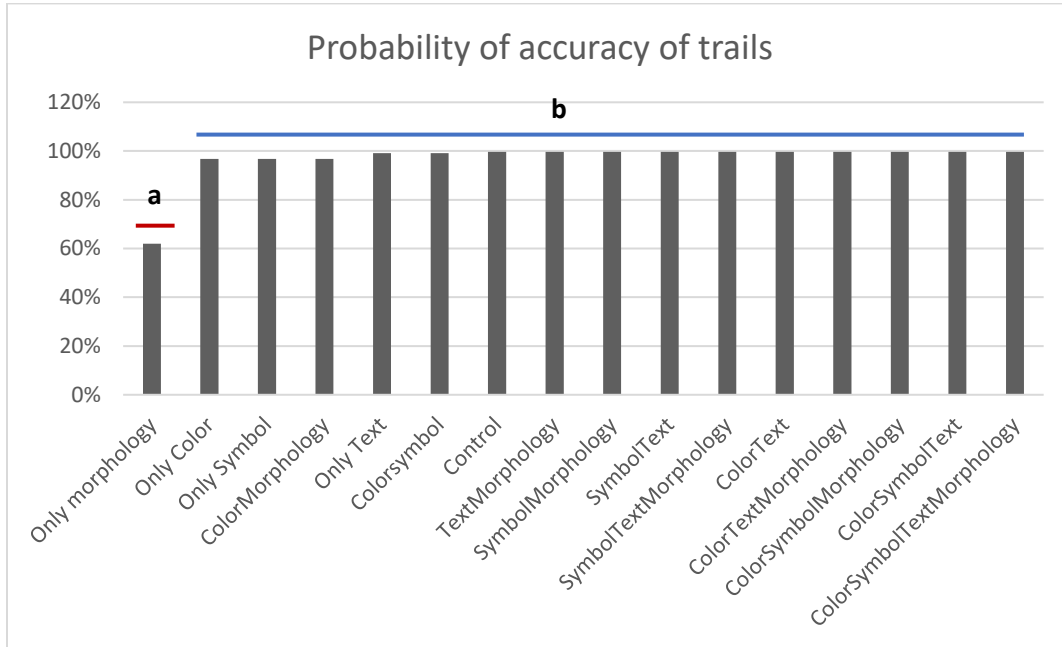


Figure 5.9: Probability of accuracy of trails using linear regression model at 95% confidence interval back transformed from logit scale, tests performed on log odds ratio scale at $\alpha=0.05$. Letters and lines indicate the significance group.

Table 5.1: p-values of the accuracy of 16 trails collapsed across the three package types and four locations. The naming pattern of the trails indicate the presence of the mentioned design cue and the absence of others. For E.g.: The trial "TextMorphology" means text and morphology are present, but color and symbol are absent.

	Only morphology	Only Text	TextMorphology	Only symbol	Symbol Morphology	Symbol Text	Symbol TextMorphology	Onlycolor	ColorMorphology	ColorText	ColorTextMorphology	ColorSymbol	ColorSymbolMorphology	ColorSymbolText	ColorSymbolTextMorphology
Control	0.014183	0.999999	1	0.9996341	1	1	1	0.95787	0.999634	1	1	0.99999	1	1	1
OnlyMorphology		3.5E-05	3.50E-05	1.30E-06	0.014183	0.014183	0.014183	2.49E-08	1.30E-06	0.014183	0.014183	3.50E-05	0.014183	0.014183	0.0141828
OnlyText			0.99999875	1	0.999999	0.999999	0.999999	0.98836	1	0.999999	1	1	0.999999	0.999999	0.9999987
TextMorphology				0.9996341	1	1	1	0.95787	0.999634	1	1	0.999999	1	1	1
OnlySymbol					0.999634	0.999634	0.999634	0.999623	1	0.999634	0.999634	1	0.999634	0.999634	0.9996341
SymbolMorphology						1	1	0.95787	0.999634	1	1	0.999999	1	1	1
SymbolText							1	0.95787	0.999634	1	1	0.999999	1	1	1
SymbolTextMorphology								0.95787	0.999634	1	1	0.999999	1	1	1
Color									0.999623	0.95787	0.95787	0.98836	0.95787	0.95787	0.9578697
ColorMorphology										0.999634	0.999634	1	0.999634	0.999634	0.9996341
ColorText											1	0.999999	1	1	1
ColorTextMorphology												0.999999	1	1	1
ColorSymbol													0.999999	0.999999	0.9999987
ColorSymbolMorphology														1	1
ColorSymbolText															1

5.3 Response Time

To further explore the research objectives, we also assessed the independent variables for possible effects on the continuous variable, participant time to correct response (the time required for each trial correctly identified) using a generalized linear mixed model. Included in the model were possible effects of age, experience, design cues (which were crossed with each other), location, package type and their influence on the overall response time. To meet normality assumptions, the confidence intervals calculated are performed on a logit scale and back transformed from the logit scale at 95%. Hypothesis testing was performed on the log odd ratio scale at $\alpha=0.05$.

The Linear Mixed model with age, experience, design cues and package types were used as predictors to check for any correlation between participant age and time to correct response. Unlike the accuracy results, the predicted model suggests that increasing age increases the response time

($p=0.0363$) at $\alpha=0.05$. A T-test was conducted to test this hypothesis which resulted in an estimate of 0.01145 (SE 0.0053) and t-value of 2.148. This indicates that for everyone year increase in age, the response time increases by about 1.15%. Figure 5.9 shows a linear relationship between age and response time; people get slower with their accurate responses as they get older.

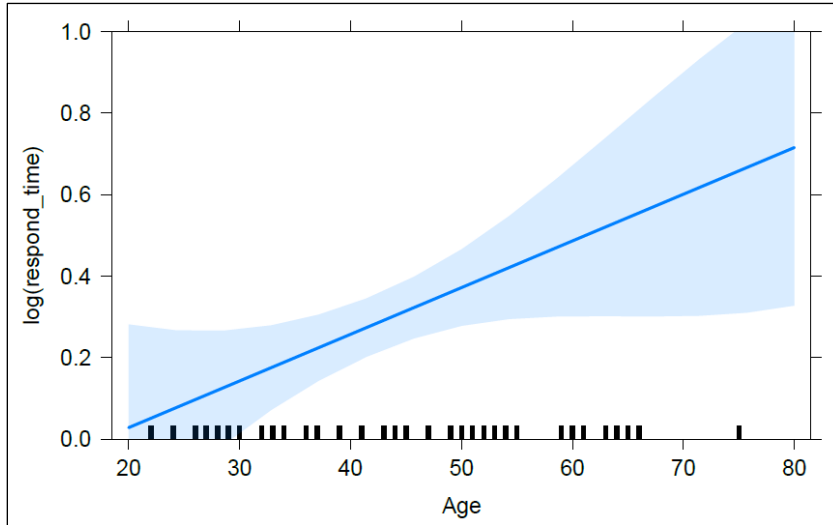


Figure 5.10: Graph plot of age v/s response time using confidence level of 95% and $\alpha=0.05$.

The average response time of trails that were correctly identified for all 56 participants exhibit a right-skewed distribution (see Figure 5.10). The majority of response times cluster between 0-2.5 seconds. This skewness suggests that most of the responses occur quickly and the responses with longer response times are less frequent. See figure 5.11.

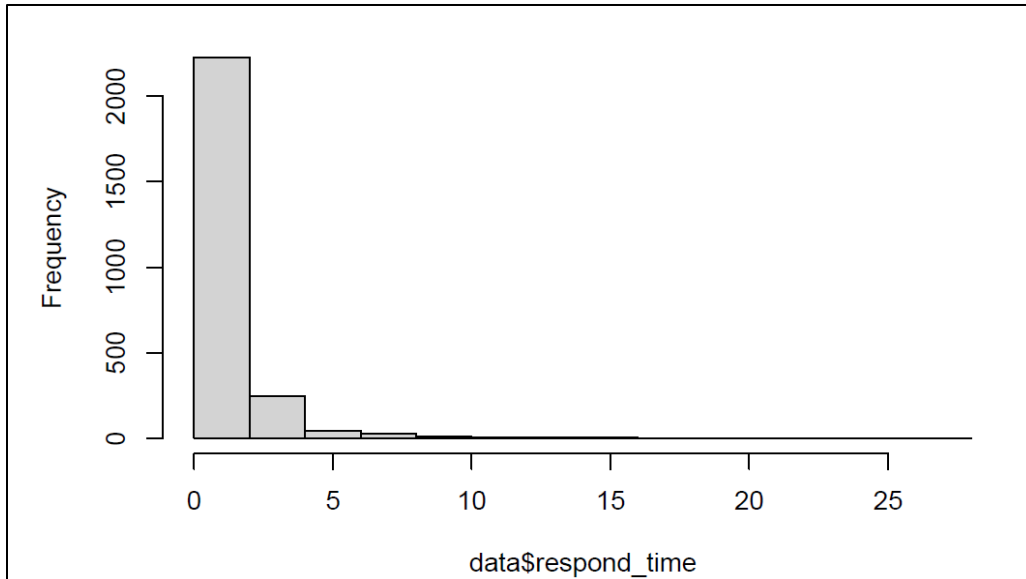


Figure 5.11: Frequency of time to correct response of 56 participants towards each design cues across the three package types.

To begin to examine reaction time (for correct responses) by location across all package types, and all trails were calculated at 95% confidence intervals, $\alpha=0.05$ (See Figure 5.12). Opening location affected the time to correct responses ($P<0.0001$). Specifically, location 5 required the longest time to be correctly identified (LSM 2.26 seconds; SE 0.1546 seconds), while locations 3 and 1 yielded the quickest time to be correctly identified (LSM 1.17 seconds; SE 0.0460 seconds), but had no evidence of difference when compared to one another. Location 7 displayed a significant difference in time to correct response, significantly more than location 1 and 3 but significantly less than location 5 (LSM 1.29 seconds; SE 0.0508 seconds), falling in group b. Location 9 showed a nuanced difference in time to correct response (LSM 1.24 seconds; SE 0.0487 seconds) falling in group ab. (Refer table 5.2 for p values).

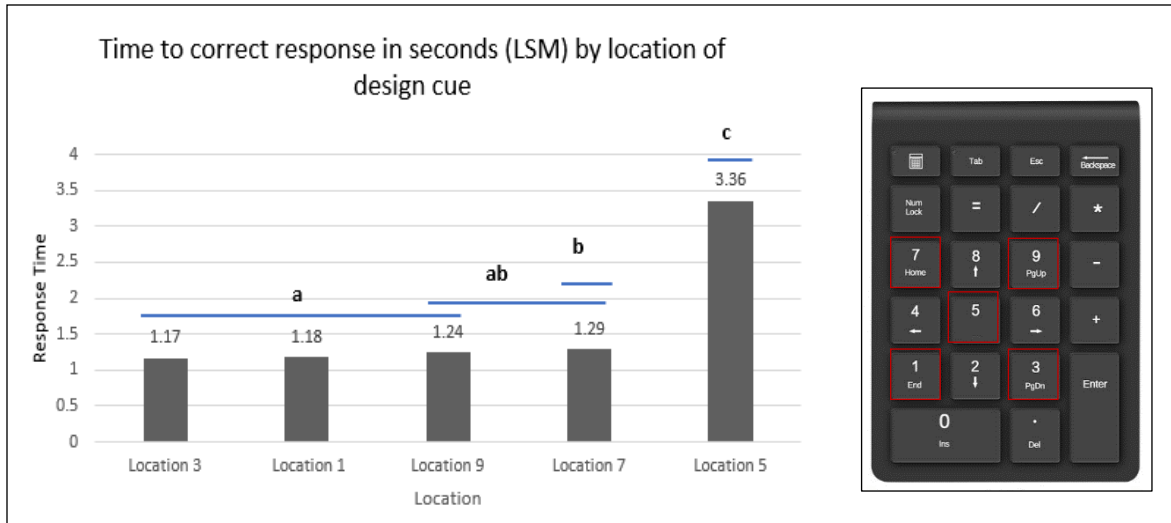


Figure 5.12: Average time to correct response by location, collapsed across the three package types and 16 design trails using the number pad to select responses.

Table 5.2: p-values of significant effects in time to correct response (LSM) by location.

	Location 3	Location 5	Location 7	Location 9
Location 1	0.987	<0.0001	0.0002	0.1693
Location 3		<0.0001	<0.0001	0.0493
Location 5			<0.0001	<0.0001
Location 7				0.2402

5.4 Average Response Time by Sets

When the time to correct response were categorized by the program number to evaluate any significant difference between the four sets, it was observed that the sets have 0 variance which suggest that the set number did not affect the time to correct response ($p=0.4353$). That is, participants across all programs exhibited no evidence of statistically significant performance related to time to correct response.

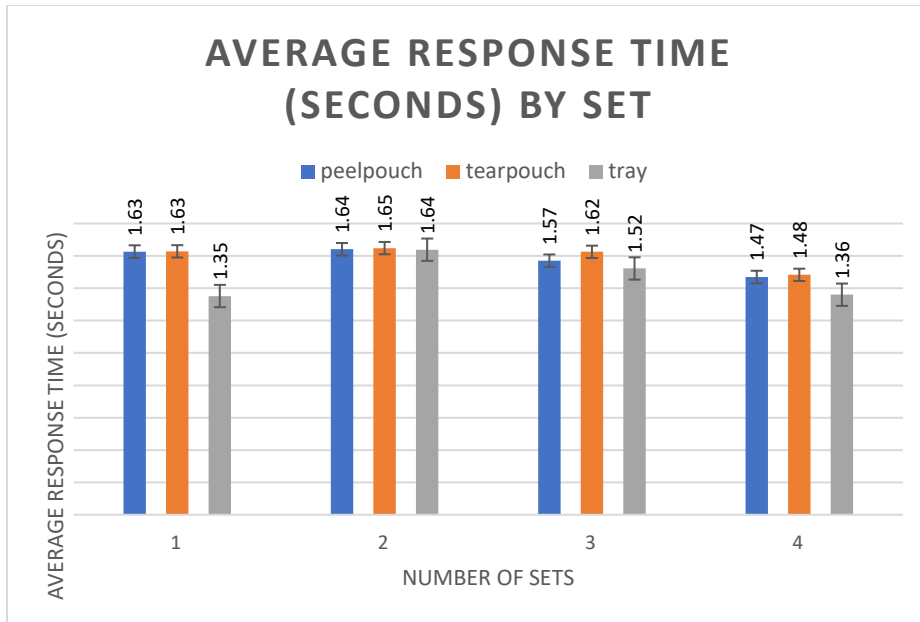


Figure 5.13: Categorizing the average time to correct response by program sets and package type.

5.5 Effect of Design cues on package types

Data collapsed across four design cues; four locations suggested that the package types had influence on the time to correct response ($p < 0.0001$). As such, analysis was conducted to identify the trails with least and highest time to correct response for each of the three package types (Peel pouch, Tray package, Tear pouch), averaged over the four design cues, and confidence level of 95% and $\alpha = 0.05$.

When time to correct response (LSM values) of all trails were examined by package type, at confidence level of 95% at $\alpha = 0.05$, data suggested that trails within thermoform trays observed quicker time to correct response compared to peel pouch or tear pouch (LSM 1.28 seconds, SE 0.0481 seconds). There is no evidence of statistical significance in time to correct responses between trails within peel pouches (LSM 1.33 seconds, SE 0.0502 seconds) and tear pouches (LSM 1.37 seconds, SE 0.0515 seconds). Refer table 5.3 for p-values and figure 5.14.

Table 5.3: p-values of the interaction between peel pouch, tear pouch and thermoform tray.

	Tear Pouch	Thermoform Tray
Peel Pouch	0.1807	0.0262
Tear Pouch		<0.0001

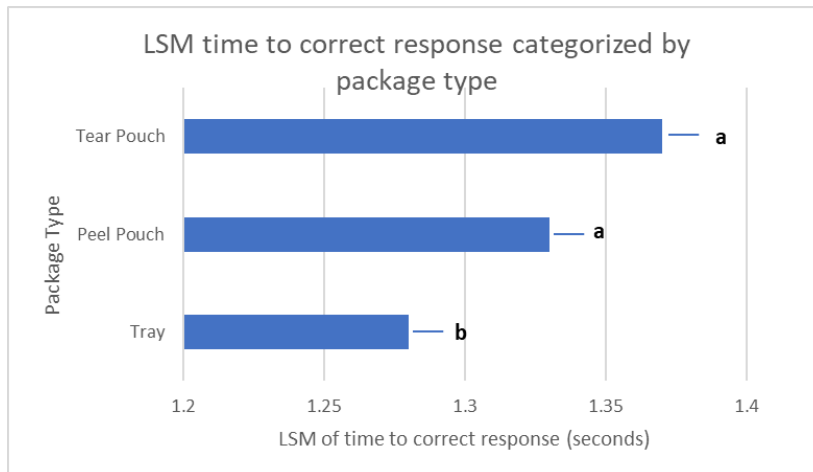


Figure 5.14: The LSM time to correct response for the 3 package types averaged over all combinations of color, symbol, text, morphology. Letters and lines indicating the statistical significance.

5.6 Effect of Package type and Design cues on participant response time (RT) for correct responses

Anova results indicate a significant main effect of design cues on the time to correct response ($P < 0.0001$). Treatments that had design cues resulted in quicker time to correct response than the trials without design cues (control trial). It is important to note that there was a significant interaction of design cue by package type at $p < 0.0001$. The effect of each design cue on times to correct response is examined independently, and the interaction between cue and package type, are explored subsequently.

Figure 5.15 presents box whisker plots representing times to correct response by package type (peel pouch, tear pouch, tray) for all design cue combinations. The figure suggests that in trials where color, symbol, text, morphology are absent (control trial) data tends to be more variable, with longer time to correct responses. Conversely, when at least one design cue is present, time to correct response is reduced and less variable in nature. The “only morphology” trial (color_no, symbol_no, text_no, morphology_yes) does not follow the same pattern as other design cues but flows the pattern of control trials resulting in variable data and longer time to correct responses. This observation was subsequently explored in further analysis.

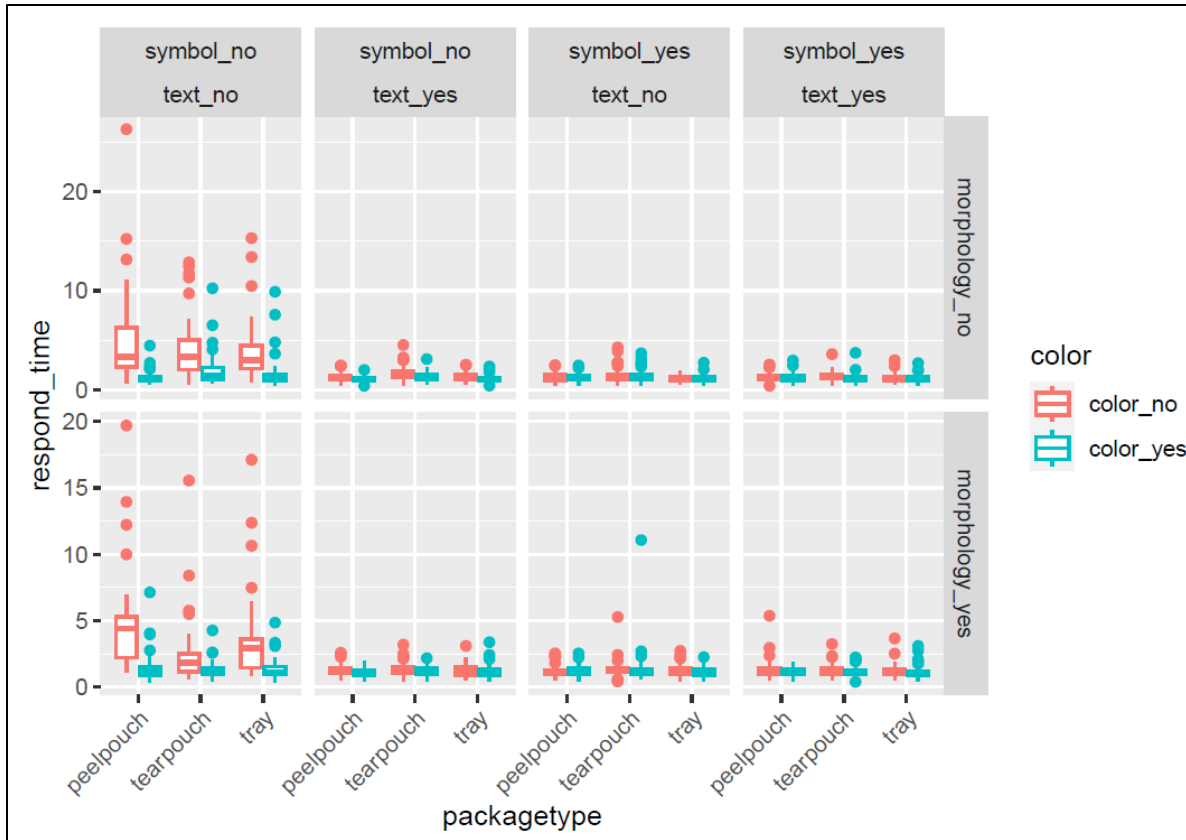


Figure 5.15: Box whisker plot of variation in response times across package types and design cues.

5.6.1 Peel Pouch

Analyzing the 16 trials within peel pouch trials, it can be observed that the control trial and only morphology trial fall under one group of statistical significance, while the remaining 14 trials performed statistically faster with regard to participants' ability to identify the correct location. This means there is no evidence of significant difference between the time to correct response between only morphology and the control trial, but their time to correct response is significantly more than the remaining 14 trials in peel pouch ($p < 0.0001$). See figure 5.16 for time to correct response of each trial within peel pouch and a complete table of p values for all comparisons in Table 5.4.

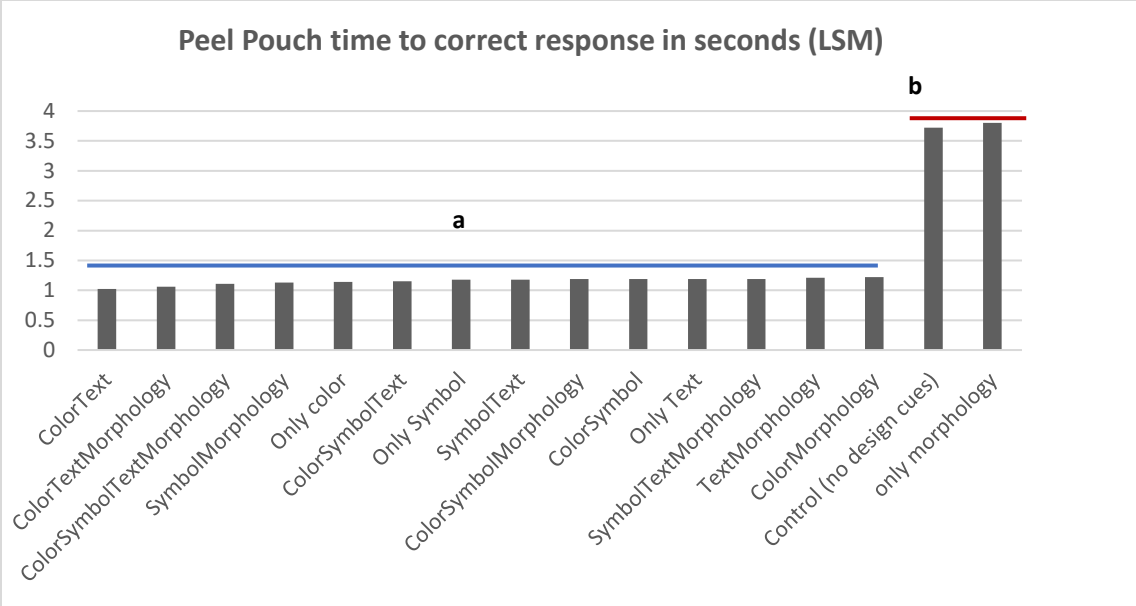


Figure 5.16: Response time of design cues in peel pouch with letters to denote their statistical significance, averaged over the four design cues, and confidence level of 95% and $\alpha=0.05$.

Table 5.4: p-values of comparisons between time to correct response of 16 trails in peel pouch across the four locations. The naming pattern of the trails indicate the presence of the mentioned design cue and the absence of others. For E.g.: The trial "TextMorphology" means text and morphology are present, but color and symbol are absent.

	Only Morphology	Only Text	Text Morphology	Symbol	Symbol Morphology	Symbol Text	Symbol Text Morphology	Color	Color Morphology	Color Text	Color Text Morphology	Color Symbol	Color Symbol Morphology	Color Symbol Text	Color Symbol Text Morphology
Control	1	< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001
Only Morphology		< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001
onlyText			1	1	0.999936	1	1	1	1	0.49786	0.8586411	1	1	1	0.998917
TextMorphology				1	0.997751	1	1	0.99975	1	0.28051	0.6591417	1	1	0.999955	0.985691
Symbol					0.999996	1	1	1	1	0.62907	0.9285778	1	1	1	0.999845
SymbolMorphology						0.9999847	0.99991506	1	0.992902	0.97648	0.9997496	1	0.999977	1	1
SymbolText							1	1	1	0.57112	0.9013623	1	1	1	0.999612
SymbolTextMorphology								1	1	0.48254	0.8483963	1	1	1	0.998677
Color									0.998857	0.92988	0.9977447	1	1	1	1
ColorMorphology										0.20549	0.5538916	1	1	0.999724	0.966851
ColorText											1	0.5185	0.551727	0.880201	0.995564
ColorTextMorphology												0.8717	0.891007	0.993332	0.999992
ColorSymbol													1	1	0.999179
ColorSymbolMorphology														1	0.999484
ColorSymbolText															1

5.6.2 Thermoform Tray

Trials that were conducted using thermoform trays show a similar trend, resulting in the same pattern of results relating to design cues; specifically, two groups of statistical significance emerge from the data. One group containing the only morphology treatments and control trails in one group resulting in statistically significantly larger times to an accurate response than the remaining 14 ($p < 0.0001$). See figure 5.17 for time to correct response of each trial within thermoform tray and a complete table of p values for all comparisons in Table 5.5.

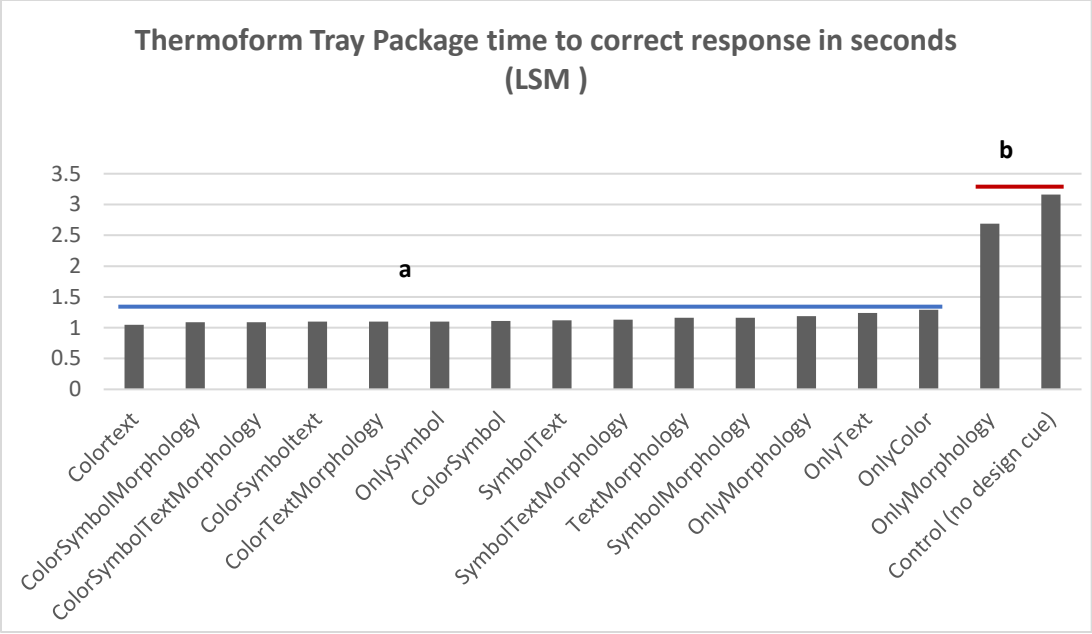


Figure 5.17: Response time of design cues in tray package with letters to denote their statistical significance, averaged over the four design cues, and confidence level of 95% and $\alpha=0.05$.

Table 5.5: p-values of comparisons between time to correct response of 16 trails in thermoform tray package across the four locations. The naming pattern of the trails indicate the presence of the mentioned design cue and the absence of others. For E.g.: The trial "TextMorphology" means text and morphology are present, but color and symbol are absent.

	Only Morphology	Only Text	Text Morphology	Symbol	Symbol Morphology	Symbol Text	Symbol Text Morphology	Only Color	Color Morphology	Color Text	Color Text Morphology	Color Symbol	Color Symbol Morphology	Color Symbol Text	Color Symbol Text Morphology
Control	0.650138	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
Only Morphology		<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
Only Text			0.999702	0.902068	0.9997313	0.96128	0.9881669	0.999999	0.9999991	0.3958328	0.898292	0.944912	0.7664806	0.88868	0.7697579
Text Morphology				0.999988	1	1	1	0.951221	1	0.9737156	0.999986	0.999999	0.9995945	0.9999803	0.9996174
Symbol					0.9999865	1	1	0.484543	0.9986977	0.9999939	1	1	1	1	1
Symbol Morphology						1	1	0.953307	1	0.9723515	0.999984	0.999999	0.9995523	0.9999774	0.9995773
Symbol Text							1	0.636254	0.9998625	0.9998743	1	1	1	1	1
Symbol Text Morphology								0.773017	0.9999926	0.9988328	1	1	0.9999992	1	0.9999993
Only Color									0.9954002	0.0876187	0.477449	0.583617	0.3048649	0.4602268	0.3080332
Color Morphology										0.8578539	0.998572	0.999677	0.9889279	0.9982217	0.9893149
Color Text											0.999995	0.999952	1	0.9999966	1
Color Text Morphology												1	1	1	1
Color Symbol													1	1	1
Color Symbol Morphology														1	1
Color Symbol Text															1

5.6.3 Tear Pouch

By contrast, design cues in trials conducted in with tear pouches resulted in a different pattern of data related to time to correct response. The design trial with only morphology and control trial lies in 2 separate groups, indicating the time to correct response are significantly different ($p < 0.0001$), the control trial having the longest time to identify the correct response, followed by only morphology trial. The rest of the 14 trails are divided into 3 distinct groups of significance. See figure 5.18 for time to correct response of each trial within thermoform tray and a complete table of p values for all comparisons in Table 5.6.

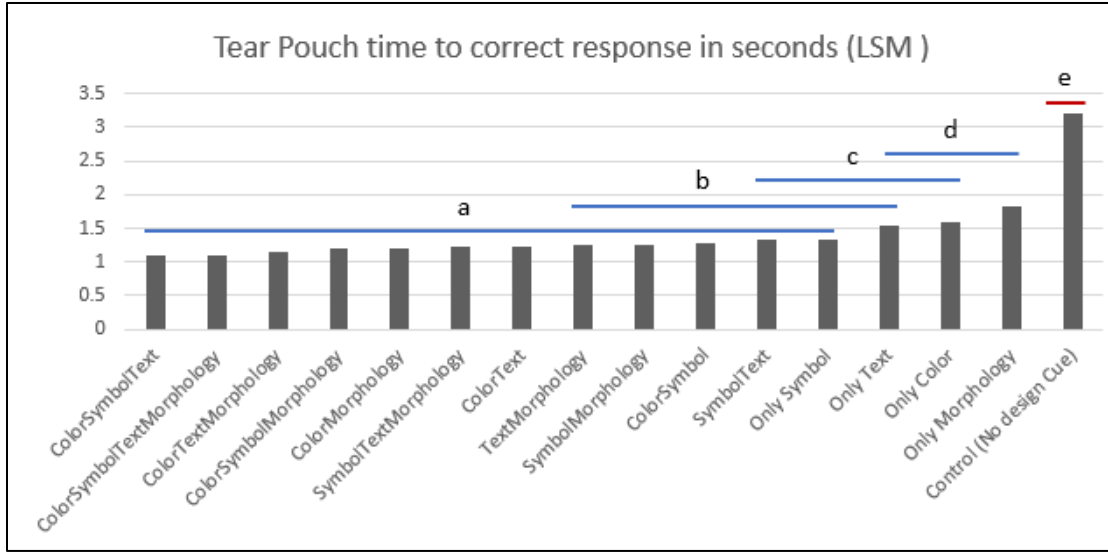


Figure 5.18: Response time of design cues in tear pouch with letters to denote their statistical significance, averaged over the four design cues, and confidence level of 95% and $\alpha=0.05$.

Table 5.6: p-values of comparisons between time to correct responses of 16 trails in tear pouch. The naming pattern of the trails indicate the presence of the mentioned design cue and the absence of others. For E.g.: The trial "TextMorphology" means text and morphology are present, but color and symbol are absent.

	Only Morphology	Only Text	Text Morphology	Symbol	Symbol Morphology	Symbol Text	Symbol Text Morphology	Color	Color Morphology	Color Text	Color Text Morphology	Color Symbol	Color Symbol Morphology	Color Symbol Text	Color Symbol Text Morphology
Control	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
OnlyMorphology		0.425549	3.50E-07	7.96E-05	3.51E-07	3.51E-05	2.05E-08	0.786623	1.22E-08	8.39E-08	< 0.0001	1.67E-06	3.02E-09	< 0.0001	< 0.0001
OnlyText			0.040015	0.472094	0.040119	0.361897	0.007445	1	0.0054074	0.01753	6.89E-05	0.0925429	0.00226152	2.48E-06	3.32E-06
TextMorphology				0.999844	1	0.999977	1	0.007002	0.9999999	1	0.9818917	1	0.99999444	0.749914	0.7828997
Symbol					0.999846	1	0.987652	0.175552	0.9792453	0.997951	0.4850645	0.9999977	0.93639104	0.132275	0.1511543
SymbolMorphology						0.999977	1	0.007024	0.9999999	1	0.9818005	1	0.99999436	0.749385	0.7824027
SymbolText							0.995471	0.117314	0.99156	0.999477	0.5841565	0.9999999	0.96762713	0.182901	0.2068383
SymbolTextMorphology								0.000989	1	1	0.9996904	0.9999996	1	0.957646	0.967808
Color									0.0006875	0.002652	5.47E-06	0.0193847	0.00025724	1.50E-07	2.05E-07
ColorMorphology										1	0.9998864	0.9999842	1	0.972756	0.9799279
ColorText											0.9969249	1	0.99999997	0.883489	0.9046829
ColorTextMorphology												0.9235575	0.99999558	1	0.9999999
ColorSymbol													0.99971161	0.550324	0.5895275
ColorSymbolMorphology														0.993279	0.9955082
ColorSymbolText															1

5.7 Statistical analysis of Effect of presence and absence of each of the four design cues collapsing across the three-package type.

When results related to time to correct response were collapsed across all package types and opening locations, and design factors trials were combined into those that are either expressed, or failed to express a given design characteristic (i.e., those with or without color, for instance), LSM comparisons suggested that the presence of all of the tested design cues made a statistically significant difference in terms of time to correctly identify the opening feature. (See Figure 5.19).

Figure 5.19 compares the four design cues on two levels (presence and absence) and their significant differences.

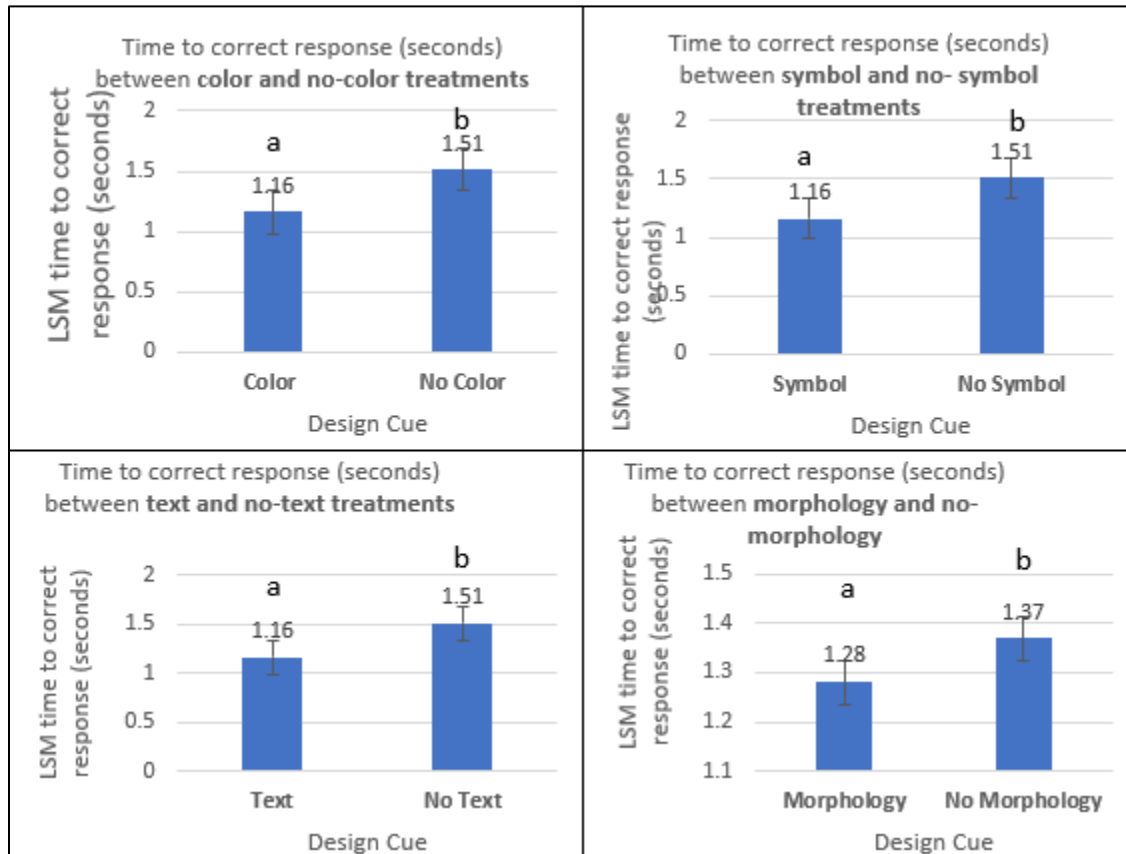


Figure 5.19: Comparison of the LSM time to correct response time between the presence and absence of the four design cues collapsed across the three package types, using 95% confidence level, $\alpha=0.05$ and letters to denote statistical significance differences.

Comparisons of LSM time to correct response of trials for all trials that included color was 1.16 seconds (SE 0.0430 seconds), while for trials with no color was 1.51 seconds (SE 0.0563 seconds) which is a statistically significant difference with $p < 0.0001$. The presence and absence of symbol also displayed a significant difference in the time taken to respond correctly. The LSM time to correct response in presence of symbol was 1.16 seconds (SE: 0.0432 seconds) and absence of symbol was 1.51 seconds (SE 0.0560 seconds), $p < 0.0001$. LSM to correct response time was 1.16 seconds (SE 0.0431 seconds) for text presence and 1.51 seconds (SE 0.0561 seconds) for text absence with $p < 0.0001$. The response to correct time for the presence and absence of morphology was significantly different ($p < 0.0001$); morphology presence was 1.28 seconds (SE 0.047 seconds) and morphology absence was 1.37 seconds (SE 0.0508 seconds).

5.8 Comparisons across three design cues

The following tables and data focus on the how the presentation of design cues influence the response dynamics.

5.8.1 Color: Symbol: Text

Herein, we present the effect that the three design cues and their resultant effect on the time to correct response. Figure 5.9.1 provides a visual that enables comparison of the predicted response time for trials with and without symbol, color and text in all possible combinations. Trials that included none of the three design cues resulted in a visibly notable increase in response as compared to all other expressions of design. The comparison of this to others (as well as all other comparisons) is formally tested in the following section.

5.8.1 a) Effect of color on the two levels of text and symbol

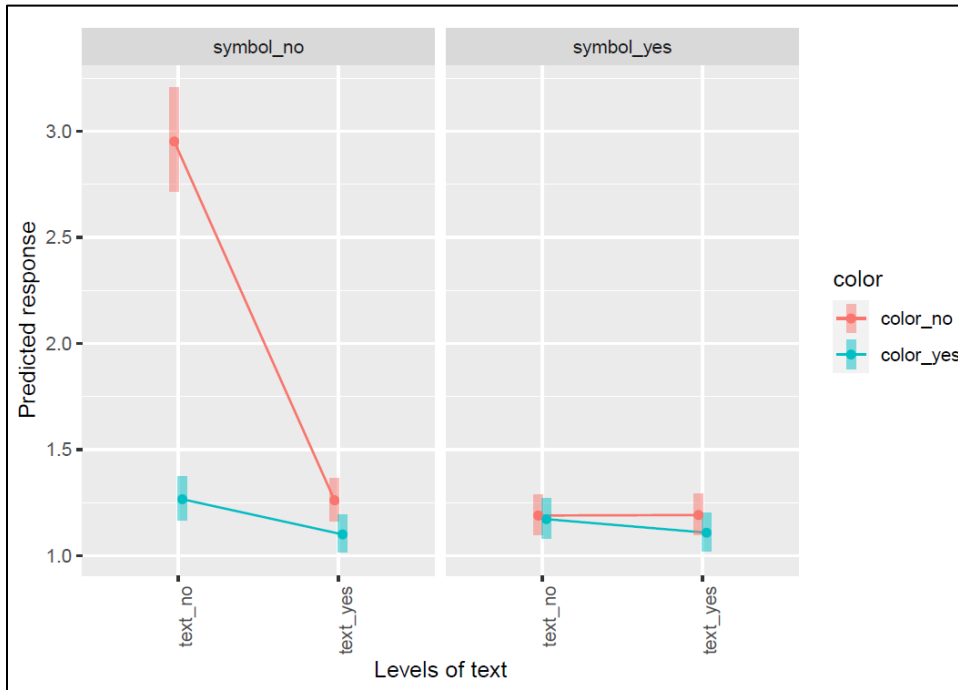


Figure 5.20: Graph plot describing the effect of color on the two levels of symbol and text.

In table 5.7, and figure 5.20, the presence of color (color_yes) speeds up the time to correct response significantly (LSM 1.27 seconds; SE 0.0508) in trails where the symbol and text are absent (symbol_no, text_no). The absence of color when symbol and text are also absent (color=no (text_no, symbol_no) led to longer time to correct response (LSM 2.95 seconds; SE 0.1221 seconds; $p < 0.0001$). This suggests that in trails where color is present, but text and symbol absent (color_yes (text=no, symbol=no)) the presence of color enhances the time to correct response.

Table 5.7: Effect of color on the absence of text (text=no) and symbol at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Text=no, Symbol=no							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
Color_yes	1.27	0.0508	78.5	1.15	1.39	a	<0.0001
Color_no	2.95	0.1221	88.7	2.69	3.24	b	<0.0001

Table 5.8 shows the comparison effect of color on the presence of text (text=yes) but absence of symbol (symbol=no). Color shows significant effect in the time to correct response, with presence of color speeding up the time to correct response when text and symbol both are absent (color_yes (text=yes, symbol=no)) (LSM 1.1 seconds; SE 0.4441; $p<0.0001$) compared to absence of color, text and symbol ((color_no) text=yes, symbol=no) (LSM 1.26 seconds; SE 0.0506 seconds; $p<0.0001$).

Table 5.8: Effect of color on the presence of text (text=yes) but absence of symbol (symbol=no) at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Text=yes, Symbol=no							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
Color_yes	1.1	0.4441	78.3	1	1.21	a	<0.0001
Color_no	1.26	0.0506	78.3	1.15	1.38	b	<0.0001

When text is absent (text=no) but symbol is present (symbol=yes), the effect of color shows no evidence of significant difference ($p=0.5628$). See table 5.9.

Table 5.9: Effect of color on the absence of text (text=no) but presence of symbol (symbol=yes) at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Text=no, Symbol=yes							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
Color_yes	1.17	0.047	78.3	1.07	1.28	a	0.5628
Color_no	1.19	0.0477	78.4	1.08	1.3	a	0.5628

When comparing trials with text, symbol and color present to trials where text and symbol was present but color was absent (LSM 1.11 seconds; SE 0.0444; to LSM 1.19 seconds; SE 0.0478 seconds, respectively), significant differences were noted, with the additional design cue speeding time to accurate identification ($p=0.0039$). See table 5.10.

Table 5.10: Effect of color on the presence of both text (text=yes) and symbol (symbol=yes) at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Text=yes, Symbol=yes							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
Color_yes	1.11	0.0444	78.3	1.01	1.21	a	0.0039
Color_no	1.19	0.0478	78.3	1.09	1.31	b	0.0039

5.9.1 b) Effect of text on the two levels of color and symbol:

Figure 5.21 shows the effect of text on the two levels of color and symbol.

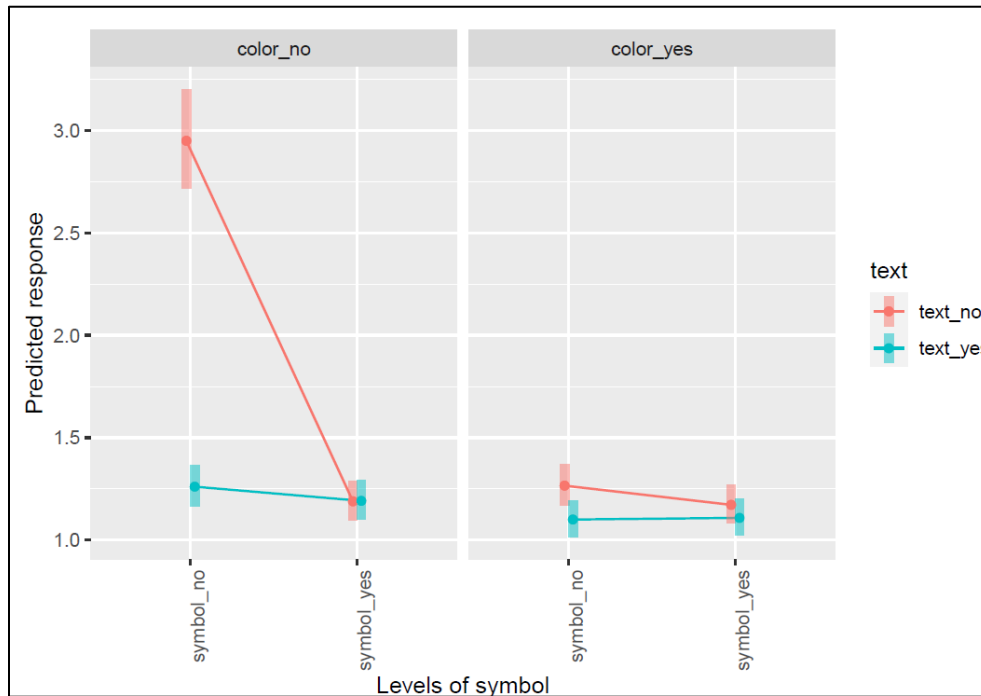


Figure 5.21: Graph plot describing the effect of text on the two levels of color and symbol.

The presence of text enables quicker time to correct response in the absence of color (color=no) and symbol (symbol=no) (LSM 1.26 seconds; SE 0.0506 seconds; $p < 0.0001$) compared to when all three design cues are absent (color=no, symbol=no, text_no) (LSM 2.95; SE 0.1221; $p < 0.0001$). See table 5.11.

Table 5.11: Effect of text on the absence of color and symbol at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Color=no, Symbol=no							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
text_yes	1.26	0.0506	78.3	1.15	1.38	a	<0.0001
text_no	2.95	0.1221	88.7	2.69	3.24	b	<0.0001

The presence of text (text_yes) when color is present, but symbol is absent results in quicker time to correct response (LSM 1.27 seconds; SE 0.0508 seconds; $p < 0.0001$). When text is absent (text_no), the time to correct response goes up (LSM 1.27 seconds; SE 0.0508 seconds; $p < 0.0001$). see table 5.12 and figure 5.21.

Table 5.12: Effect of text on the presence of color but absence of symbol at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Color=yes, Symbol=no							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
text_yes	1.1	0.0441	78.3	1	1.21	a	<0.0001
text_no	1.27	0.0508	78.5	1.15	1.39	b	<0.0001

Table 5.13 suggests that the presence or absence of text shows no evidence of significant effect for trails where color is absent (color) but symbol is present (symbol=yes) ($p=0.9392$).

Table 5.13: Effect of text on the absence of color but presence of symbol at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Color=no, Symbol=yes							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
text_yes	1.19	0.0477	78.4	1.08	1.3	a	0.9392
text_no	1.19	0.0478	78.3	1.09	1.31	a	0.9392

The presence of all three design cues (text_yes, color=yes, symbol=yes) results in quicker time to correct response (LSM 1.11 seconds; SE 0.0444; $p=0.0255$) compared to when text is absent (text_no, color=yes, symbol=yes) (LSM 1.17 seconds; SE 0.047 seconds; $p=0.0255$). See table 5.14 and figure 5.21.

Table 5.14: Effect of text on the presence of both color and symbol at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Color=yes, Symbol=yes							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
text_yes	1.11	0.0444	78.3	1.01	1.21	a	0.0255
text_no	1.17	0.047	78.3	1.07	1.28	b	0.0255

5.9.1 c) Effect of symbol on the two levels of color and text

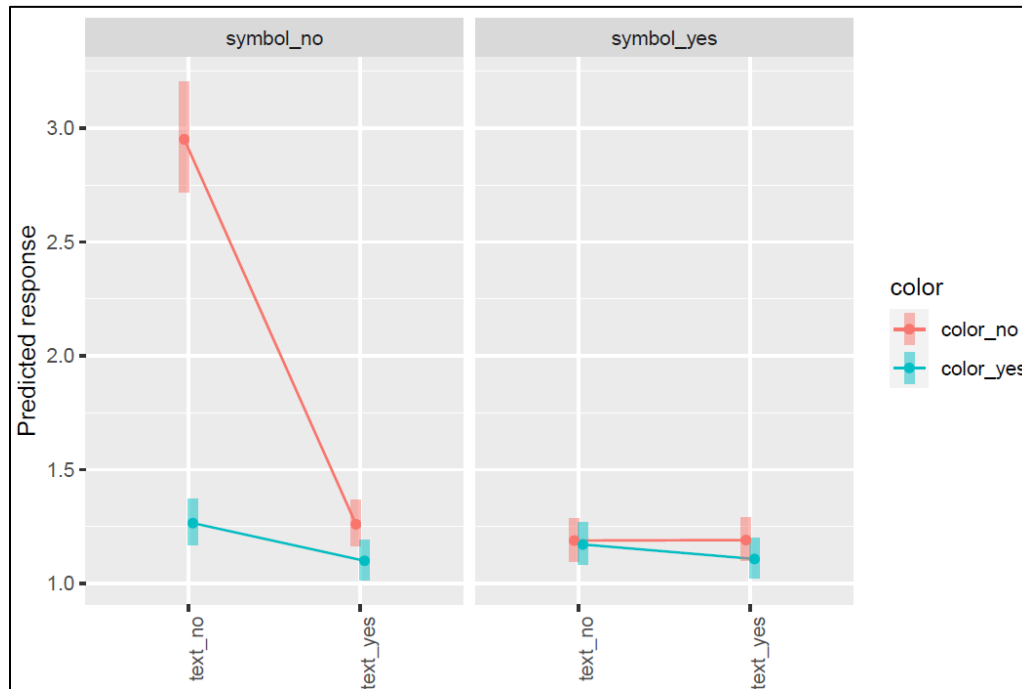


Figure 5.22: Graph plot describing the effect of symbol on the two levels of color and text.

Table 5.15 and figure 5.22 suggests the presence of symbol (symbol_yes) results in significant reduced time to correct response when color and text are both absent (color=no, text=no) (LSM 1.19 seconds; SE 0.0477 seconds; $p<0.0001$) compared to when all three design ques are absent (symbol_no, color=no, text=no)(LSM 2.95 seconds; SE 0.0508 seconds; $p<0.0001$).

Table 5.15: Effect of symbol on the absence of color and text at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Color=no, Text=no							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
symbol_yes	1.19	0.0477	78.3	1.07	1.28	a	<0.0001
symbol_no	2.95	0.0508	78.5	1.15	1.39	b	<0.0001

The presence of symbol (symbol_yes) speeds up the time to correct response when color is present, but text is absent (color=yes, text=no) (LSM 1.17 seconds; SE 0.047 seconds; p=0.0021). The absence of symbol (symbol_no) increases the time to correct response (LSM 1.27 seconds; SE 0.0508 seconds; p=0.0021). See table 5.16 and figure 5.22.

Table 5.16: Effect of symbol on the presence of color but absence of text at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Color=yes, Text=no							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
symbol_yes	1.17	0.047	78.3	1.07	1.28	a	0.0021
symbol_no	1.27	0.0508	78.5	1.15	1.39	b	0.0021

The presence of symbol (symbol_yes) results in significant reduction in time to correct response in the below table also (Table 5.24) when color is absent but text is present (color=no, text=yes) (LSM 1.19 seconds; SE 0.0478 seconds; p=0.0239) compared to when symbol is absent (symbol_no) (LSM 1.26 seconds; SE 0.0506; p=0.0239). See table 5.17 and figure 5.22.

Table 5.17: Effect of symbol on the presence of text but absence of color at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Color= no, Text=yes							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
symbol_yes	1.19	0.0478	78.3	1.09	1.31	a	0.0239
symbol_no	1.26	0.0506	78.3	1.15	1.38	b	0.0239

The effect of symbol shows no evidence of significant difference when the color and text both are present (color=yes, text=yes), ($p=0.7721$). See table 5.18.

Table 5.18: Effect of symbol on the presence of both text and color at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Color= yes, Text=yes							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
symbol_yes	1.1	0.0441	78.3	1	1.21	a	0.7721
symbol_no	1.11	0.0444	78.3	1.01	1.21	a	0.7721

5.8.2 Symbol: Morphology: Color

The tables and graphs in this section explore the interaction between symbol, morphology and color and their effect on the time to correct response.

5.8.2 a) Effect of symbol on the two levels of morphology and color.

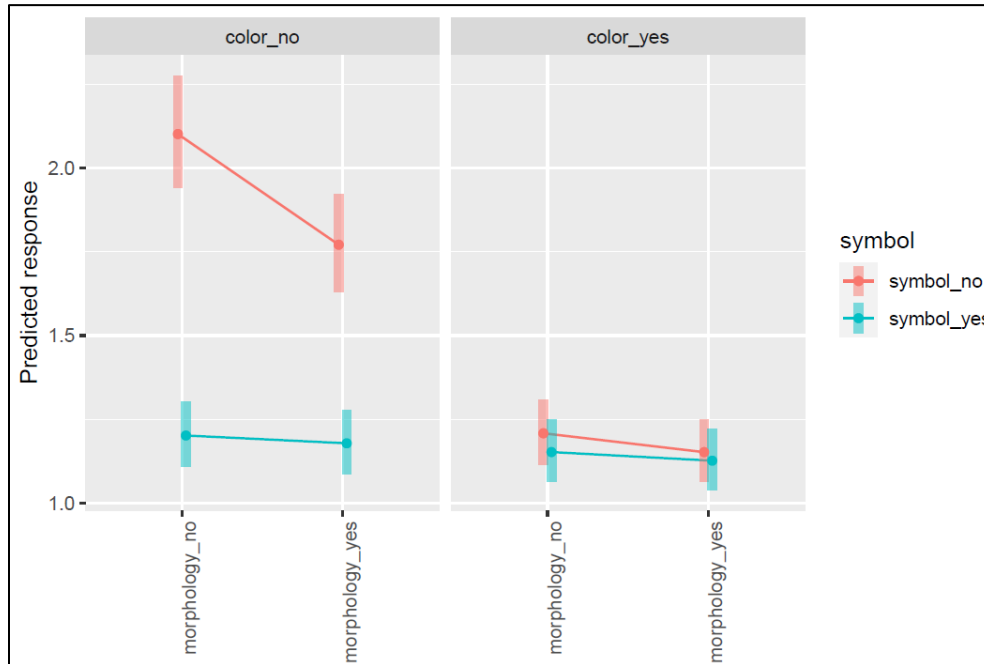


Figure 5.23: Graph plot describing the effect of symbol on the two levels of color and morphology. Table 5.30 and figure 5.23 suggests that the presence of symbol (symbol_yes) enables quicker time to correct response when color and morphology both are absent (color=no, morphology=no) (LSM 1.2 seconds; SE 0.0482; $p < 0.0001$). The absence of all three design cues results in significant increase in the time to correct response (LSM 2.1 seconds; SE 0.0842; $p < 0.0001$).

Table 5.19: Effect of symbol on the absence of both color and morphology at 95% confidence interval, $\alpha = 0.05$ and their respective p values.

Color=no, Morphology=no							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
symbol_yes	1.2	0.0482	78.4	1.1	1.32	a	<0.0001
symbol_no	2.1	0.0842	78.3	1.92	2.3	b	<0.0001

The effect of symbol shows no significant effect when color is present, but morphology is absent (color=yes, morphology=no) ($p = 0.0585$). see table 5.20.

Table 5.20: Effect of symbol on the presence of color but absence of morphology at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Color=yes, Morphology=no							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
symbol_yes	1.15	0.0462	78.3	1.05	1.26	a	0.0585
symbol_no	1.21	0.0485	78.5	1.1	1.32	a	0.0585

Table 5.21 and figure 5.23 suggests that presence of symbol (symbol_yes) results in reduced time to correct response when color is absent, but morphology is present (color=no, morphology=yes) (LSM 1.18 seconds; SE 0.0473 seconds; $p<0.0001$) compared to the absence of symbol (symbol_no) (LSM 1.77 seconds; SE 0.0733 seconds; $p<0.0001$).

Table 5.21: Effect of symbol on the absence of color but presence of morphology at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Color=no, Morphology=yes							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
symbol_yes	1.18	0.0473	78.3	1.08	1.29	a	<0.0001
symbol_no	1.77	0.0733	88.7	1.61	1.95	b	<0.0001

Symbol shows no significant effect in time to correct response when color and morphology both are present (color=yes, morphology=yes) ($p=0.3719$). See table 5.22.

Table 5.22: Effect of symbol on the presence of both color and morphology at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Color=yes, Morphology=yes							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
symbol_yes	1.13	0.0452	78.3	1.03	1.23	a	0.3719
symbol_no	1.15	0.0462	78.3	1.05	1.26	a	0.3719

5.9.2 b) Effect of morphology on the two levels of color and symbol

The tables in this section focus on the interaction between the morphology color and symbol, identifying the effect of morphology on the two levels of color and symbol and their influence of their presence and absence on the time to correct response.

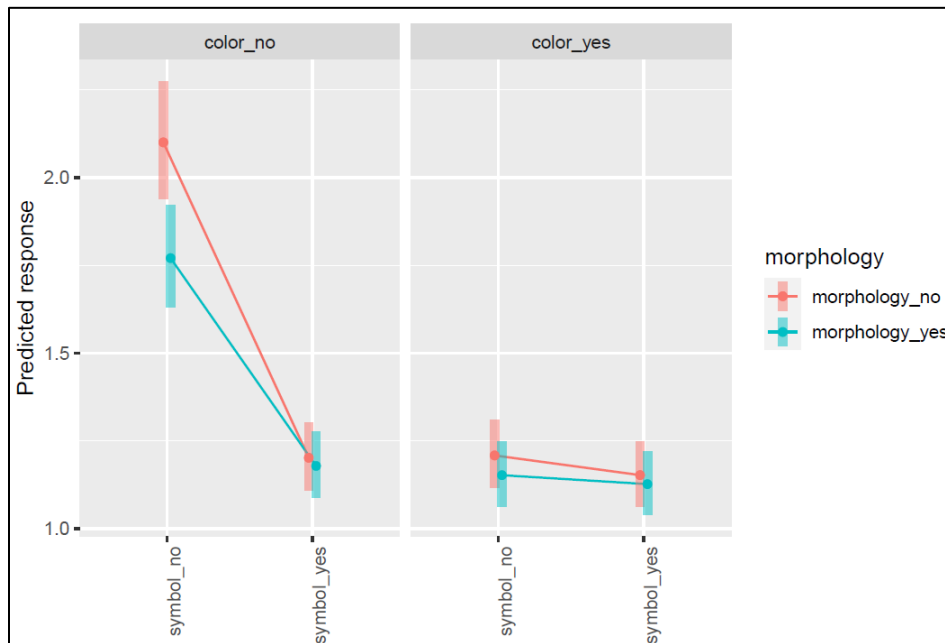


Figure 5.24: Graph plot describing the effect of symbol on the two levels of color and symbol.

From table 5.23 and figure 5.24, it can be observed that the presence of morphology (morphology_yes) enables quicker time to correct response when color and symbol both are absent (color=no, symbol=no) (LSM 1.77 seconds; SE 0.0733 seconds; $p<0.0001$). The absence of all

thee design cues (morphology_no, color=no, symbol=no) significantly increases the time to correct response (LSM 2.1 seconds; SE 0.0843 seconds; $p < 0.0001$).

Table 5.23: Effect of morphology on the absence of both color and symbol at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Color=no, Symbol=no							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
morphology_yes	1.77	0.0733	88.7	1.61	1.95	a	<0.0001
morphology_no	2.1	0.0843	78.3	1.92	2.3	b	<0.0001

The effect of morphology has no significant difference when color is present, but symbol is absent (color=yes, symbol=no) ($p=0.0575$). See table 5.24.

Table 5.24: Effect of morphology on the presence of color but absence of symbol at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Color=yes, Symbol=no							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
morphology_yes	1.15	0.0462	78.3	1.05	1.26	a	0.0575
morphology_no	1.21	0.0584	78.5	1.1	1.32	a	0.0575

Referring to table 5.25, the effect of morphology has no significant difference when color is absent, but symbol is present (color=no, symbol=yes) ($p=0.4359$).

Table 5.25: Effect of morphology on the absence of color but presence of symbol at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Color=no, Symbol=yes							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
morphology_yes	1.18	0.0473	78.3	1.08	1.29	a	0.4359
morphology_no	1.2	0.0482	78.4	1.1	1.32	a	0.4359

The effect of morphology has no significant difference when there both color and symbol present (color=yes, symbol=yes). See table 5.26.

Table 5.26: Effect of morphology on the presence of both color and symbol at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Color=yes, Symbol=yes							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
morphology_yes	1.13	0.0452	78.3	1.03	1.23	a	0.3676
morphology_no	1.15	0.0462	78.3	1.05	1.26	a	0.3676

We can observe from tables 5.23 above that morphology shows reduction in time to correct response when color and symbol both are absent. In the presence of at least one of the two design cues or both (color and symbol), morphology shows no significant difference see table 5.24, 5.25, 5.26.

5.9.2 c) Effect of color on the two levels of symbol and morphology

The graph and tables in this section explore the effect of color on the two levels of symbol and morphology.

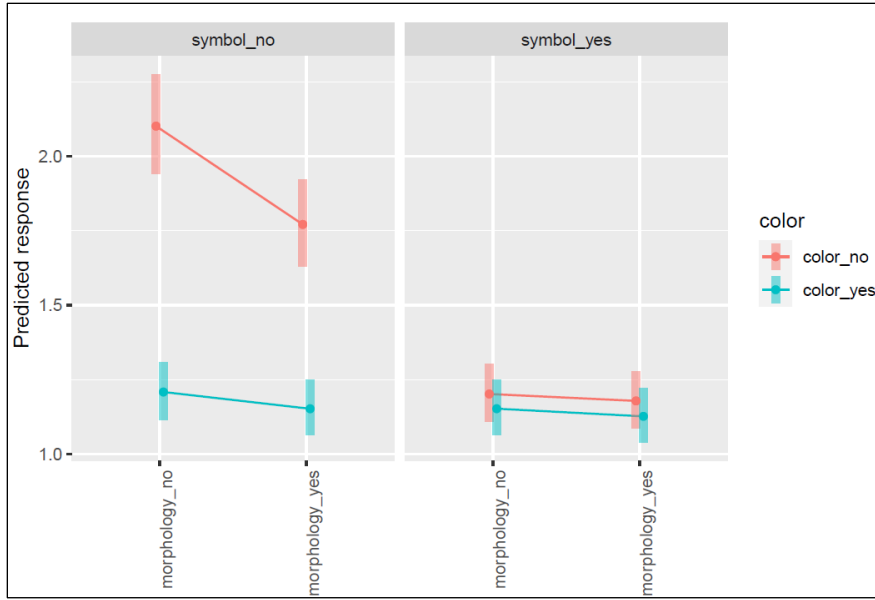


Figure 5.25: Graph plot describing the effect of color on the two levels of symbol and morphology. Table 5.27 and figure 5.25 suggests that when both symbol and morphology are absent (symbol=no, morphology=no), the presence of color (color_yes) results in significantly quicker time to correct response (LSM 1.21 seconds; SE 0.0485 seconds; $p < 0.0001$) compared to the absence of all three design cues (LSM 2.1 seconds; SE 0.0843 seconds; $p < 0.0001$).

Table 5.27: Effect of color on the absence of both symbol and morphology at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Symbol=no, morphology=no							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
color_yes	1.21	0.0485	78.5	1.1	1.32	a	<0.0001
color_no	2.1	0.0843	78.3	1.92	2.3	b	<0.0001

The results are different when symbol is present, but morphology is absent (symbol=yes, morphology=no). The effect of color shows no evidence of significant difference here. See table 5.28.

Table 5.28: Effect of color on the presence of symbol but absence of morphology at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Symbol=yes, morphology=no							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
color_yes	1.15	0.0462	78.3	1.05	1.26	a	0.0944
color_no	1.2	0.0482	78.4	1.1	1.32	a	0.0944

When symbol is absent, but morphology is present (symbol=no, morphology=yes), the presence of color (color_yes) enables quicker time to correct identification (LSM 1.15 seconds; SE 0.0462; $p<0.0001$) compared to absence of color (LSM 1.77 seconds; SE 0.0733 seconds; $p<0.0001$). See table 5.29 and figure 5.25.

Table 5.29: Effect of color on the absence of symbol but presence of morphology at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Symbol=no, morphology=yes							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
color_yes	1.15	0.0462	78.3	1.05	1.26	a	<0.0001
color_no	1.77	0.0733	88.7	1.61	1.95	b	<0.0001

When symbol and morphology both are present (symbol=yes, morphology=yes), the effect of color shows no evidence of significant difference ($p=0.0727$). See table 5.30 and figure 5.25.

Table 5.30: Effect of color on the presence of both symbol and morphology at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Symbol=yes, morphology=yes							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
color_yes	1.13	0.0452	78.3	1.03	1.29	a	0.0727
color_no	1.18	0.0473	78.3	1.08	1.29	a	0.0727

5.8.3 Symbol: Text: Morphology

The tables and figures in this section explore the interaction between symbol, text and morphology and their effect on the time to correct response.

5.8.3 a) Effect of text on the two levels of morphology and symbol

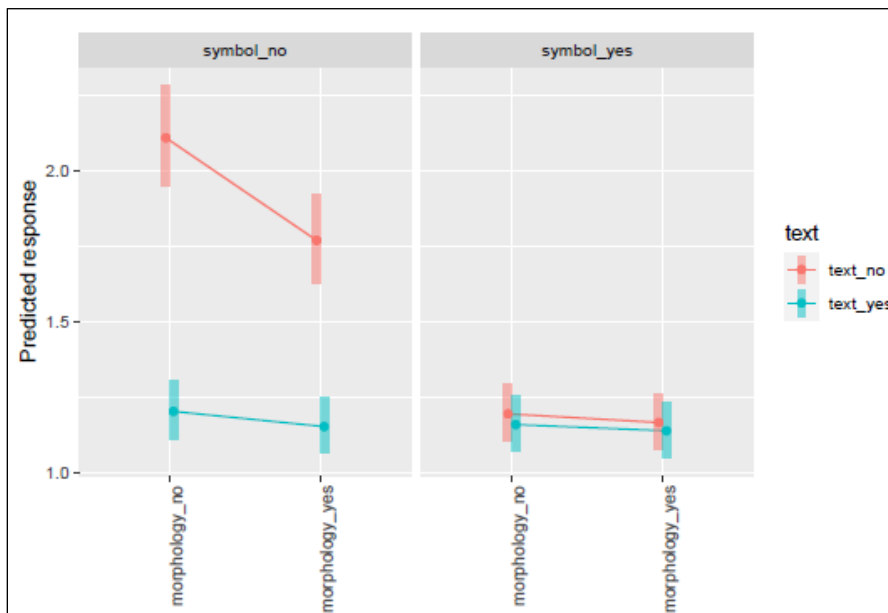


Figure 5.26: Graph plot describing the effect of text on the two levels of symbol and morphology. We can observe from table 5.31 and figure 5.26 that presence of text (text_yes) significantly reduces the time to correct response when morphology and symbol are absent (morphology=no, symbol = no) (LSM 1.2 seconds; SE 0.0482 seconds; $p<0.0001$). The absence of all three design cues (morphology=no, symbol=no, text_no) results in longer time to correct response (LSM 2.11 seconds; SE 0.0847 seconds; $p<0.0001$).

Table 5.31: Effect of text on the absence of both, symbol, and morphology at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Morphology= no Symbol= no							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
text_yes	1.2	0.0482	78.3	1.1	1.32	a	<0.0001
text_no	2.11	0.0847	78.5	1.93	2.31	b	<0.0001

The effect of text also shows a significant effect when morphology is present, but symbol is absent (morphology=yes, symbol= no). The presence of text (text_yes) enables quicker time to correct response (LSM 1.15 seconds; SE 0.0462 seconds; $p<0.0001$) compared to absence of text (LSM 1.77 seconds, SE 0.0733 seconds; $p<0.0001$). See table 5.32 and figure 5.26.

Table 5.32: Effect of text on the presence of morphology but absence of symbol at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Morphology= yes Symbol= no							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
text_yes	1.15	0.0462	78.3	1.05	1.26	a	<0.0001
text_no	1.77	0.0733	88.7	1.61	1.95	b	<0.0001

Text shows no evidence of significant effect when morphology is absent and symbol is present (morphology=no, symbol=yes) ($p=0.2275$). See table 5.33.

Table 5.33: Effect of text on the absence of morphology but presence of symbol at 95% confidence interval, $\alpha=0.05$ and their respective p values.

morphology= no Symbol= yes							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
text_yes	1.16	0.0465	78.3	1.06	1.27	a	0.2275
text_no	1.19	0.0479	78.4	1.09	1.31	a	0.2275

The effect of text also shows no evidence of significant difference when both morphology and symbol are present (morphology=yes, symbol=yes) ($p=0.3418$). See table 5.34.

Table 5.34: Effect of text on the absence of morphology but presence of symbol at 95% confidence interval, $\alpha=0.05$ and their respective p values.

morphology= yes Symbol= yes							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
text_yes	1.14	0.0457	78.3	1.04	1.25	a	0.3418
text_no	1.17	0.0468	78.3	1.06	1.28	a	0.3418

5.9.3 b) Effect of morphology on the two levels of text and symbol

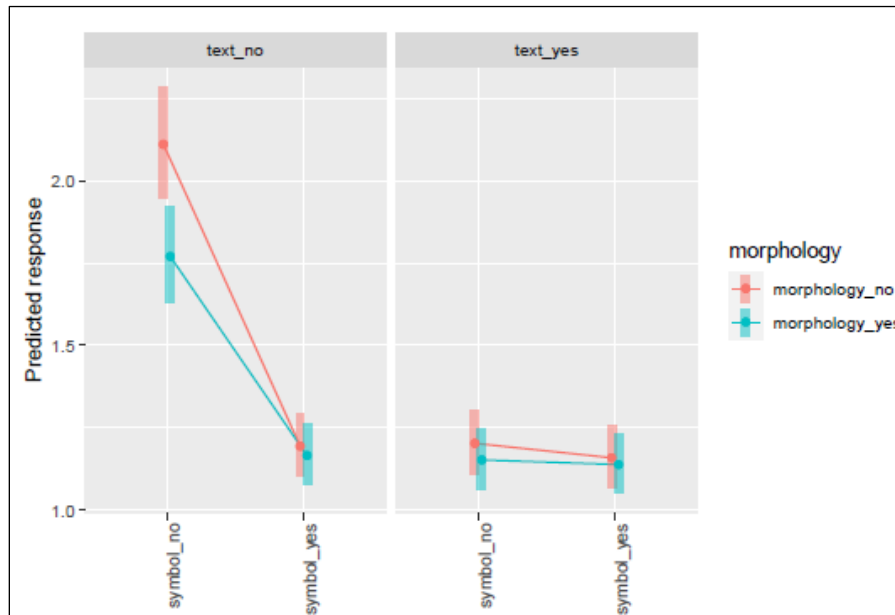


Figure 5.27: Graph plot describing the effect of morphology on the two levels of text and symbol. The presence of morphology (morphology_yes) results in quicker time to correct response when both text and symbol are absent (text=no, symbol=no) (LSM 1.77 seconds; SE 0.0733 seconds; $p < 0.0001$). The absence of all three design cues leads to longer time to correct response (text=no, symbol=no, morphology_no) (LSM 2.11 seconds; SE 0.0847 seconds; $p < 0.0001$). See table 5.35 and figure 5.27.

Table 5.35: Effect of morphology on the absence of text and symbol at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Text= no Symbol= no							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
morphology_yes	1.77	0.0733	88.7	1.61	1.95	a	<0.0001
morphology_no	2.11	0.0847	78.5	1.93	2.31	b	<0.0001

Morphology shows no evidence of significant effect when text is present, but symbol is absent (text=yes, symbol=no) ($p=0.0877$). See table 5.36.

Table 5.36: Effect of morphology on the presence of text but absence of symbol at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Text= yes Symbol= no							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
morphology_yes	1.15	0.0462	78.3	1.05	1.26	a	0.0877
morphology_no	1.2	0.0482	78.3	1.1	1.32	a	0.0877

Table 5.37 shows that morphology shows no evidence of significant effect when text is absent, but symbol is present (text=no, symbol=yes) ($p=0.333$).

Table 5.37: Effect of morphology on the absence of text but presence of symbol at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Text=no Symbol= yes							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
morphology_yes	1.17	0.0468	78.3	1.06	1.28	a	0.333
morphology_no	1.19	0.0479	78.4	1.09	1.31	a	0.333

Morphology also shows no evidence of significant effect when text and symbol both are present (text=yes, symbol=yes) ($p=0.4766$). see table 5.38.

Table 5.38: Effect of morphology on the presence of both text and symbol at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Text=yes Symbol=yes							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
morphology_yes	1.14	0.0457	78.3	1.04	1.25	a	0.4766
morphology_no	1.16	0.0465	78.3	1.06	1.27	a	0.4766

5.9.3 c) Effect of Symbol on the two levels of text and morphology

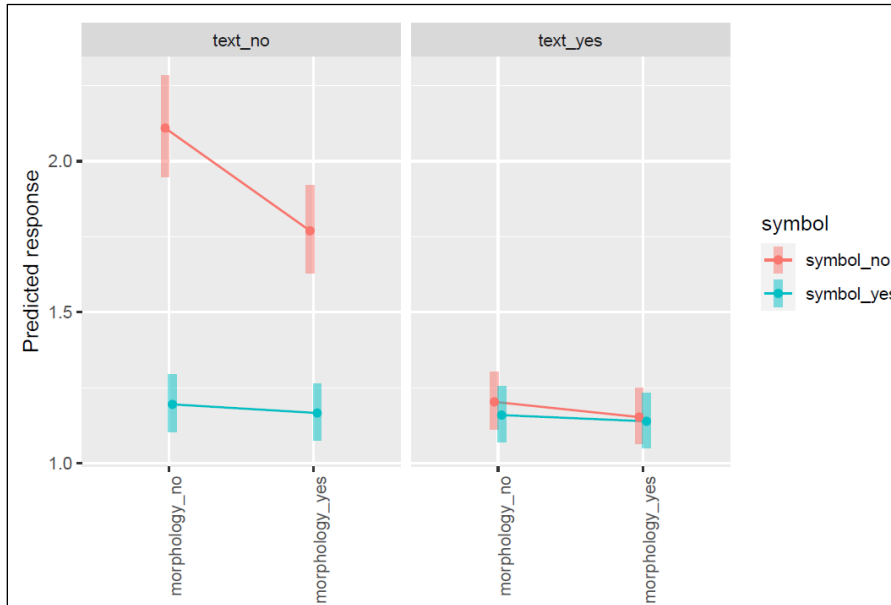


Figure 5.28: Graph plot describing the effect of symbol on the two levels of text and morphology. The presence of symbol (symbol_yes) reduces the time to correct response significantly when both, text and morphology are absent (text=no, morphology=no) (LSM 1.19 seconds; SE 0.0479 seconds; $p < 0.0001$). The absence of symbol, text and morphology (symbol_no, text=no, morphology=no) results in longer time to correct response (LSM 2.11 seconds; SE 0.0847 seconds; $p < 0.0001$). See table 5.39 and figure 5.28.

Table 5.39: Effect of symbol on the absence of both text and morphology at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Text=no Morphology=no							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
symbol_yes	1.19	0.0479	78.4	1.09	1.31	a	<0.0001
symbol_no	2.11	0.0847	78.5	1.93	2.31	b	<0.0001

When text is present and morphology is absent (text=yes, morphology=no), the effect of symbol has no evidence of significant difference on the time to correct response ($p=0.1382$). See table 5.40.

Table 5.40: Effect of symbol on the presence of text and absence of morphology at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Text=yes Morphology=no							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
symbol_yes	1.16	0.0465	78.3	1.06	1.27	a	0.1382
symbol_no	1.2	0.0482	78.3	1.1	1.32	a	0.1382

Symbol shows a significant difference in the time to correct response when text is absent, but morphology is present (text=no, morphology=yes). When symbol is present the time to correct response is quicker (LSM 1.17 seconds; SE 0.0468; $P<0.0001$), whereas when symbol is absent, the time to correct response goes up (LSM 1.77 seconds; SE 0.0462; $p<0.0001$). See table 5.41.

Table 5.41: Effect of symbol on the absence of text and presence of morphology at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Text=no Morphology=yes							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
symbol_yes	1.17	0.0468	78.3	1.06	1.28	a	<0.0001
symbol_no	1.77	0.0733	88.7	1.61	1.95	b	<0.0001

Symbol shows no evidence of significant effect when text and morphology both are present ($p=0.6265$). See table 5.42.

Table 5.42: Effect of symbol on the presence of both text and morphology at 95% confidence interval, $\alpha=0.05$ and their respective p values.

Text=yes Morphology=yes							
	LSM Time to correct response (seconds)	SE	df	Lower CL	Upper CL	Group	p-value
symbol_yes	1.14	0.0457	78.3	1.04	1.25	a	0.6265
symbol_no	1.15	0.0462	78.3	1.05	1.26	a	0.6265

6. Conclusion

Visual design cues are an important form of communication that have the potential to guide users towards intended and successful opening and use of packages of all types. Within specific contexts of healthcare, swift and accurate handling of medical device packages to accomplish aseptic transfer can be critical, with minimal room for error, or luxury to spend time if designs are not intuitive to use.

ISO 11607, Packaging for terminally sterilized medical devices, regulates that useability of sterile barrier systems (SBS) must be evaluated for the ability to identify where to begin the opening, and the ability to recognize and open without contamination or damage to the device and present the contents aseptically. This research has its focus on creating a user-centric approach to evaluate and improve the useability and identification of the opening feature by incorporating various design cues on the package.

The research's objective was to create empirical evidence of how design cues aid in information perception by a healthcare professional in a peri-operative environment. We have successfully demonstrated that the presence of design cues significantly impact time to opening such that healthcare providers are able to identify opening features more quickly when features were present (with the exception of changes to package morphology). There was not an indication of a time/accuracy trade-off for the features that positively impacted time to identification (color, symbol and text), and accuracy was at ceiling even in the control trails.

Overall, 97% of the trials were correctly identified (n= 2688) by the participants and 2.7% were incorrectly identified (n=75). Statistical analyses were conducted to investigate the correlation between the age, professional experience on the accuracy of response, which led to the conclusion that age and professional experience of the healthcare provider did not affect their ability to correctly identify opening features. However, age did significantly affect the time to correct response. Data in figure 5.10 suggested that with increasing age, the time to response also increased.

When considering the design cues, the trails with only morphology performed poorly, with both the lowest accuracy to correct identification and significantly longer response times for two out of three package types tested. Out of the 75 incorrectly identified trails, 85% (n=64) of the trails consisted of only morphology across the three package types and four corners. The probability to correctly identify only morphology trails was 62%, whereas the remaining 15 combination of

design cues provided a stronger signal to indicate the opening feature with 99% probability. When “only morphology” trails appeared on the screen in between other trails with color, symbol, text, the only morphology trial failed to provide a strong enough signal to guide them to the correct location for opening and they used the same logic as the control trial, by pressing “5” for the “only morphology trails” too. The only morphology trial was not a strong enough cue for them to differentiate from the control cue, hence having the lowest accuracy out of all other design cues. Statistical analysis suggested that the design cues have a significant influence on the response time of the package ($p < 0.0001$). When the combined effect of design cues on package type were studied, results suggested that how design cues influenced the time to correct response changed across package type ($p < 0.0001$).

In peel pouches, trials with only morphology present took the longest time for correct identification (LSM 3.80 seconds; SE 0.2852 seconds) followed by trials that tested the control trial (LSM 3.72 seconds; SE 0.2090 seconds). The presence of color and text (color_yes, symbol_no, text_yes, morphology_no) showed the quickest time to correct identification (LSM 1.02 seconds; SE 0.0576 seconds). Trials of tear pouch that tested the control trial took the longest time to correct identification (3.21 seconds; SE 0.1802 seconds) followed by only morphology trial (LSM 1.82 seconds; 0.1060 seconds). By contrasts, those trials that included Color-symbol-text (color_yes, symbol_yes, text_yes, morphology_no) resulted in the quickest times to correct response (LSM 1.10 seconds; SE 0.0617 seconds). In trials involving thermoform trays, the control trial required the longest time to correct identification (3.16 seconds; SE 0.1778 seconds) followed by only morphology trial (LSM 2.69 seconds; SE 0.1829 seconds). Color-text (color_yes, symbol_no, text_yes, morphology_no) trails enabled quickest time to correct response (LSM 1.05 seconds; SE 0.0611 seconds).

Overall, for all three packages, the presence of color and text enhanced the time to correct response for all the participants. Referring to figure 5.19, we can observe that the presence of 1 design cue reduces the overall time to correct response.

One conclusion that can be drawn from results is that the morphology approach that we took was ineffective; trials that included only morphology resulted in slow response times. Even in the package where these trails outperformed the control trials (only one See Figure 5.17) they still resulted in the lowest accuracy to be correctly across all package types.

Observing the effect of the number of design cues, it provides no evidence of significant difference between each other and that the presence of even 1 design cue is significant enough to reduce the time to correct response.

Limitations

One distinct observation noticed was the probability to identify the control cue (no design cues present) was 100%. The reason could be that participants were instructed to press the number “5” on the number-pad for the responses they didn’t observe a design cue or were unsure of correct answer. This action cannot replicate into real life situations because the medical device packages with no design cue will still have a correct opening location/feature, though not necessarily have a visual affordance guiding the user. As such, it is difficult to say for certain that the new design features would outperform existing designs (e.g. it could be that healthcare providers, through experience “intuit” where to open, and do so correctly). That said, it is important to note that the ISO standard now requiring an objective assessment of ability to accurately identify the opening feature.

Future Scope and work

Considering the above factors, it would be very useful to understand and validate the effect of the design in real contexts of care, hence performing case studies with physical prototypes and testing the various prototypes in an actual/simulated environments will provide useful insight about the effect of visual cues on the behaviors of healthcare providers in medical device packaging. Additionally, morphology performed very poorly in our study, which was somewhat surprising to us. This could be because it really isn’t a labeling feature, but a physical structural change. It is suggested that future work examines the impact of morphology in a physical context, and that different variations than the designs attempted here be examined.

The design cues tested in permutations and combinations were 4 (color, symbol, text, morphology). There needs to be data with other design elements, color combinations, package types and sizes to get an initial analysis about the perception of design cues on the opening features on medical device packages.

The approach used in this experiment can be adopted for testing various aspects of a medical device packages to form preliminary case studies, which can be used in the decision-making process of packaging development.

standardization of the design cues that can be used in the opening feature of medical device packaging approved by international standards and regulations is the next step.

REFERENCES

1. Andersen, E., Goucher-Lambert, K., Cagan, J., & Maier, A. (2021). Attention affordances: Applying attention theory to the design of complex visual interfaces. *Journal of Experimental Psychology: Applied*, 27(2), 338–351. <https://doi.org/10.1037/xap0000349>.
2. 11607-1:2019, A. (2019). ANSI/AAMI/ISO 11607-1:2019; Packaging for Terminally Sterilized Medical Devices—Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems. <https://doi.org/10.2345/9781570207211>.
3. Bergman, L. M., Pettersson, M. E., Chaboyer, W. P., Carlström, E. D., & Ringdal, M. L. (2017). Safety hazards during intrahospital transport: a prospective observational study. *Critical care medicine*, 45(10), e1043-e1049.
4. Duet. (2017, May 25). Operating room personnel input critical to new peelable Chevron header pouch. *Healthcare Packaging*. <https://www.healthcarepackaging.com/machinery-materials/flexible-packaging/news/13280850/operating-room-personnel-input-critical-to-new-peelable-chevron-header-pouch>.
5. Cai, J. (2012). Perceptions of Medical Device Packaging Used by Operating Room Personnel.
6. De la Fuente, Javier & Bix, Laura. (2009). Medical Device Packaging 10.13140/RG.2.1.1.
7. De la Fuente, J., Gustafson, S., Twomey, C., & Bix, L. (2016). Note: An Affordance-Based Methodology for Package Design. In *Packaging Technology and Science* (Vol. 29, Issue 12, p. 612). John Wiley and Sons Ltd. <https://doi.org/10.1002/pts.2276>.
8. Duet. (2017, May 25). Operating room personnel input critical to new peelable Chevron header pouch. *Healthcare Packaging*. <https://www.healthcarepackaging.com/machinery-materials/flexible-packaging/news/13280850/operating-room-personnel-input-critical-to-new-peelable-chevron-header-pouch>.
9. Gastmeier, P., Stamm-Balderjahn, S., Hansen, S., Nitzschke-Tiemann, F., Zuschneid, I., Groneberg, K., & Rüden, H. (2005). How Outbreaks Can Contribute to Prevention of Nosocomial Infection: Analysis of 1,022 Outbreaks. *Infection Control and Hospital Epidemiology*, 26(4), 357–361. <https://doi.org/10.1086/502552>.
10. Groneberg, K., & Ruden, H. (2005). How outbreaks can contribute to prevention of nosocomial infection: analysis of 1,022 outbreaks. *Infection Control and Hospital*.
11. Hegde, V. (2013) ‘Role of human factors/ usability engineering in Medical Device Design’, 2013 Proceedings Annual Reliability and Maintainability Symposium (RAMS) [Preprint]. doi:10.1109/rams.2013.6517650.
12. Gibson, J. J. (2014). *Ecological approach to visual perception: Classic Edition*. Psychology Press.
13. Gosbee, J., & Gosbee, L. L. (2007). Usability evaluation in health care. *Handbook of Human Factors and Ergonomics in Health Care and Patient Safety*. Carayon P (Ed). Mahwah, NJ, Lawrence Erlbaum Associates, 6796-6792.

14. ISO, E. (2019). 11607-1: 2009; Packaging for Terminally Sterilized Medical Devices-Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems.
15. 7000, I. (2011). ISO 7000 — Graphical symbols for use on equipment — Registered symbols. <https://www.iso.org/obp/ui#iso:grs:7000:3079>.
16. Lee, J., Cash, R. E., Crowe, R. P., Hong, H. G., Panchal, A. R., Silk, K., Helmker, M., & Bix, L. (2021b). Paramedic interactions with the packaging of medications and medical supplies: Poor package design has the potential to impact patient outcomes. PLoS ONE, 16(8 August). <https://doi.org/10.1371/journal.pone.0255099>.
17. Narins, B. (2013). The Gale Encyclopedia of Nursing and allied health. Gale Cengage Learning.
18. Norman, D. A. (n.d.). Affordance, Conventions & Design. <http://www.jnd.org>.
19. Perez, P., Bush, T. R., Hong, H. G., Pan, W., Miller, L., & Bix, L. (2018). Reducing levels of medical device contamination through package redesign and opening technique. Plos one, 13(11), e0206892.
20. Qin, S., Li, R., Yin, Y., & Fang, L. (2023). Evaluating aseptic presentation of different medical device packaging configurations. Biomedical Instrumentation & Technology, 57(3), 87–97. <https://doi.org/10.2345/0899-8205-57.3.87>.
21. Recommended practices, A. (2012). Introduction to the AORN recommended practices. Perioperative Standards and Recommended Practices, 53-56. <https://doi.org/10.6015/psrp>.
22. Trier, T., Bix, L., & Zhang, Y. (n.d.). Unpackaging Aseptic Presentation: A Qualitative Study into the Contextual Influences Involving Medical Packaging Design and Use Heuristics Among Perioperative Personnel. In Journal of Applied Packaging Research (Vol. 14).
23. Sherman, M. (Ed.). (1998). Medical Device Packaging Handbook, Revised and Expanded. CRC Press.
24. Seo, D. C., Ladoni, M., Brunk, E., Becker, M. W., & Bix, L. (2017). Do healthcare professionals comprehend standardized symbols present on medical device packaging? An important factor in the fight over label space. Packaging Technology and Science, 30(3), 61-73.
25. Bix, L., Seo, D. C., Ladoni, M., Brunk, E., & Becker, M. W. (2016). Evaluating varied label designs for use with medical devices: Optimized labels outperform existing labels in the correct selection of devices and time to select. PloS one, 11(11), e0165002.
26. Standards, recommended Practices and Guidelines. (2006). Denver: AORN Inc.

APPENDIX A: APPROVED FORMS AND DOCUMENTS

A.1. Research Participant Consent Form

Effect of Design cues like color, symbol, text, morphology on the opening tab of medical device packaging for quick identification and aseptic presentation

Researcher and Title: Dr. Laura Bix, Professor | Prutha Kedar, Graduate Student

Department and Institution: School of Packaging, Michigan State University

Contact Information: kedarpru@msu.edu | +1 517-944-7875

Sponsor: Dr. Laura Bix, Assistant Dean for Teaching, Learning and Academic Analytics.

Professor, School of Packaging

BRIEF SUMMARY (*This is a general informed consent requirement*)

You are being asked to participate in a research study. Researchers are required to provide a consent form to inform you about the research study, to convey that participation is voluntary, to explain risks and benefits of participation including why you might or might not want to participate, and to empower you to make an informed decision. You should feel free to discuss and ask the researchers any questions you may have.

PURPOSE OF THIS RESEARCH

We hypothesize that emphasizing the signal of opening feature of a medical device package using design cues like color, symbol, morphology, or shape will enable quicker identification and ensure aseptic presentation which are extremely crucial in time intense environment like healthcare setups.

Participation Criteria

- Currently working or have a history of employment as a healthcare professional and have experience with aseptic presentation
- Student pursuing a professional healthcare course
- 18 years of older

YOUR PARTICIPATION IN THIS

Your participation in this study will take up to 35 minutes

Pretest Data

Before beginning the experiment, we will characterize your background by asking a few questions on age, gender, and work experience. We will ask you to read the smallest line of a card consisting of a series of lines or text of different font sizes as a measure of your visual acuity. We will also ask you to read a series of numbers made of colored dots from a booklet.

Experiment

You will be asked to sit Infront of a computer screen. We will conduct a visual acuity test and a color vision test. The results from the visual acuity test and color vision test along with other demographics like profession, number of years of experience will be entered into the program. Once the details are input into the system, the screen will generate a summary of the provided details. You can verify the details and confirm to proceed ahead. The screen will then display an instruction sheet of how the experiment functions. We will first conduct a practice session, to get you used to the experiment. You will be informed once the practice session ends, and the actual experiment is about to begin, if you have any questions or doubts this would be the right time to ask the researcher assisting you.

For each experiment, a series of 48 medical device labels will appear on the screen one by one. You need to observe the label, quickly identify the design cue, and press a number on the number pad that represents that specific corner (Details will be mentioned on the instruction sheet in the program). After the experiment concludes, the researcher will finalize your participation by verifying your information and ensuring the compensation is provided.

POTENTIAL BENEFITS

Your contribution to this study will be useful for the medical device packaging industry. This will help us understand how design features facilitate quick identification for opening medical device packages.

POTENTIAL RISKS

There cannot be any potential risks from this experiment. You will be asked to sit in front of a computer screen for this experiment for approximately 20-30 minutes.

PRIVACY AND CONFIDENTIALITY

All the data collected will be kept confidential. Your information collected will be stored and referred to as a subject number and hence will not be identified with your name or any other personal detail. The information will be stored in a secure computer on the campus of Michigan State University for a minimum of 3 years after the research is completed.

YOUR RIGHTS TO PARTICIPATE, SAY NO OR WITHDRAW

You have the right to say no to participating in the research. You can stop at any time after it has already started. There will be no consequences if you stop, and you will not be criticized or you will not lose any benefits that you normally receive. Participation is voluntary, you may choose not to participate at all, or you may refuse to participate in certain procedures or answer certain questions or discontinue your participation at any time without consequence.

COSTS AND COMPENSATION FOR BEING IN THE STUDY

You will receive \$50 in exchange for your participation in this study. Even if you do not complete some portions of the study or choose to withdraw from this study altogether, you will still receive the \$50.

CONTACT INFORMATION

If you have concerns or questions about this study, such as scientific issues, how to do any part of it, or to report an injury, please contact the researcher, Laura Bix (448, Wilson Road, East Lansing, 48824) bixlaura@msu.edu

If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University’s Human Research Protection Program at 517-355-2180, Fax 517-432-4503, or e-mail irb@msu.edu or regular mail at 4000 Collins Rd, Suite 136, Lansing, MI 48910.

DOCUMENTATION OF INFORMED CONSENT

Your signature below means that you voluntarily agree to participate in this research study.

Signature

Date

Signature of Assenting Child (13-17; if appropriate)

Date

You will be given a copy of this form to keep.

A.2. Flyer for inviting eligible participants for study



School of Packaging

Participants needed for a Research Study at MSU School of Packaging

Research Area : Effect of Design cues like color, symbol, text, morphology on the opening feature of medical device packaging for quick identification



To Participate:

- 18 years of older
- Currently working or have a history of employment as a healthcare professional and have experience with aseptic presentation
- Currently a student enrolled in a healthcare program and have completed training in aseptic presentation or have practical experience in aseptic technique as a part of your healthcare program

Your Participation in this:
Series of medical device labels will be presented on the screen to which you need to observe and select the opening corner that facilitates aseptic presentation



Time required for experiment : 20 minutes
Compensation: \$50



For further details and to schedule your appointment, contact:
Prutha Kedar, Ms Packaging Science :
Email: kedarpru@msu.edu
Phone : +1 517-512-4743

Figure A1: Flyer to share the details of the study to eligible participants.

A.3. Pretest Form

AAMI Research study Pretest Questions			
Subject Number			
Session Number			
Age			
Sex identified at birth	Female	Male	Self-Identified Gender
Profession			
Number of years in this profession			
Visual Acuity result			
Color vision test result			

Figure A2: Pretest form for participants.

A.4. Visual Acuity and Color vision sheet

COHZ	20/400
SZND C	20/320
VKCN R	20/250
KCRHN	20/200
ZKDVC	20/160
HVORK	20/125
DRNSK R HSON	20/100
OKSVZ KSVRH	20/80
KSNHO HNKCD	20/63
HOVSN NDVKO	20/50
VCSZH DHOSZ	20/40
CZDVR VNRDO	20/32
SHRZC CZHKS	20/25
DNOKR ORZSK	20/20
HZSCV SCNDZ	20/16
CKRDZ NDHKC	20/12.5
RDONK VKORH	20/10

How many-colored symbols do you see?

What are they?


Where are they? 

Figure A3: Visual acuity sheet.

A.5. Pseudoisochromatic plates

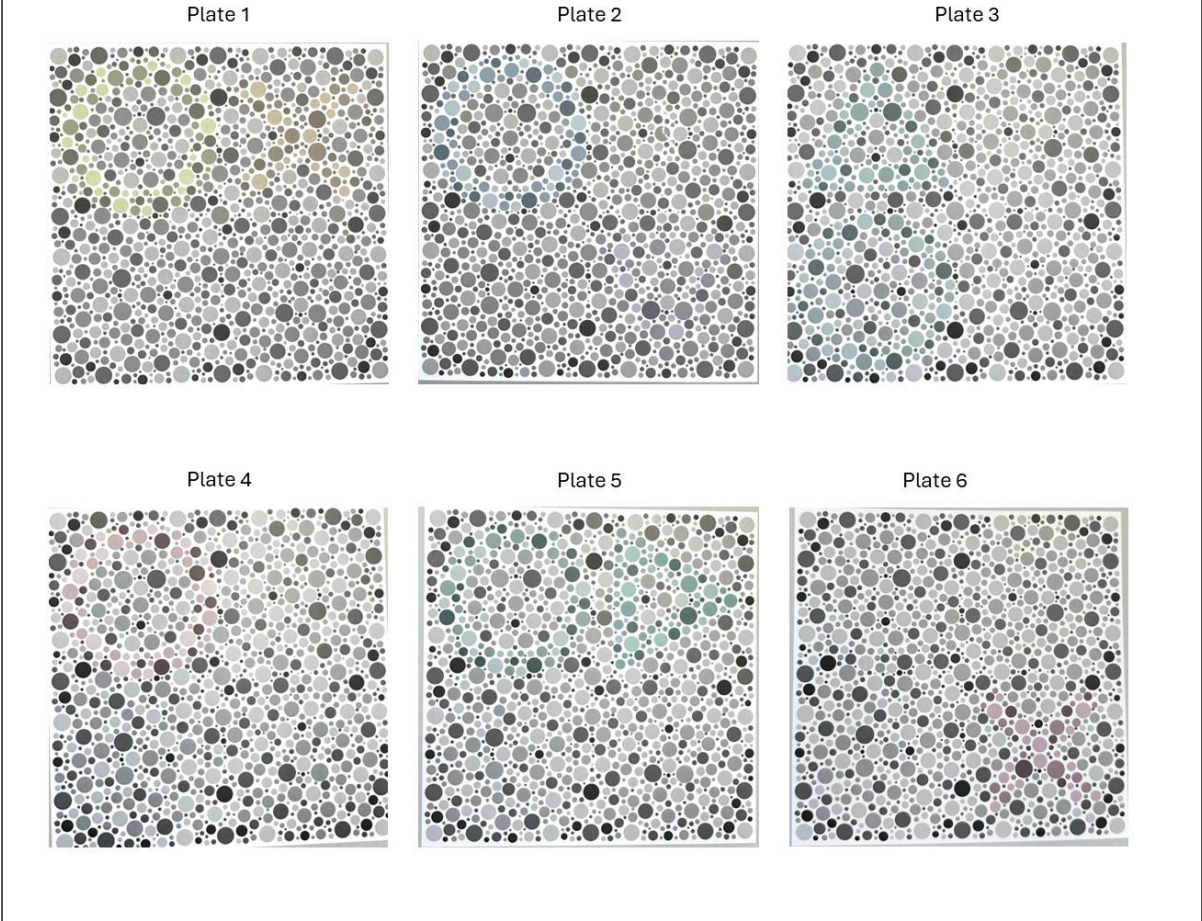


Figure A4: Pseudoisochromatic plates for color vision test.

APPENDIX B: TRIAL IMAGE FILES

B.1. Practice Trails

Practice trial 1.

Practice trial 2.

Practice trial 3.

Practice trial 4.

Figure B1: Four Practice Trials for participants.

B.2. Peel Pouch Image Files



Figure B2: Part 1 of design cues on the four locations of peel pouch.

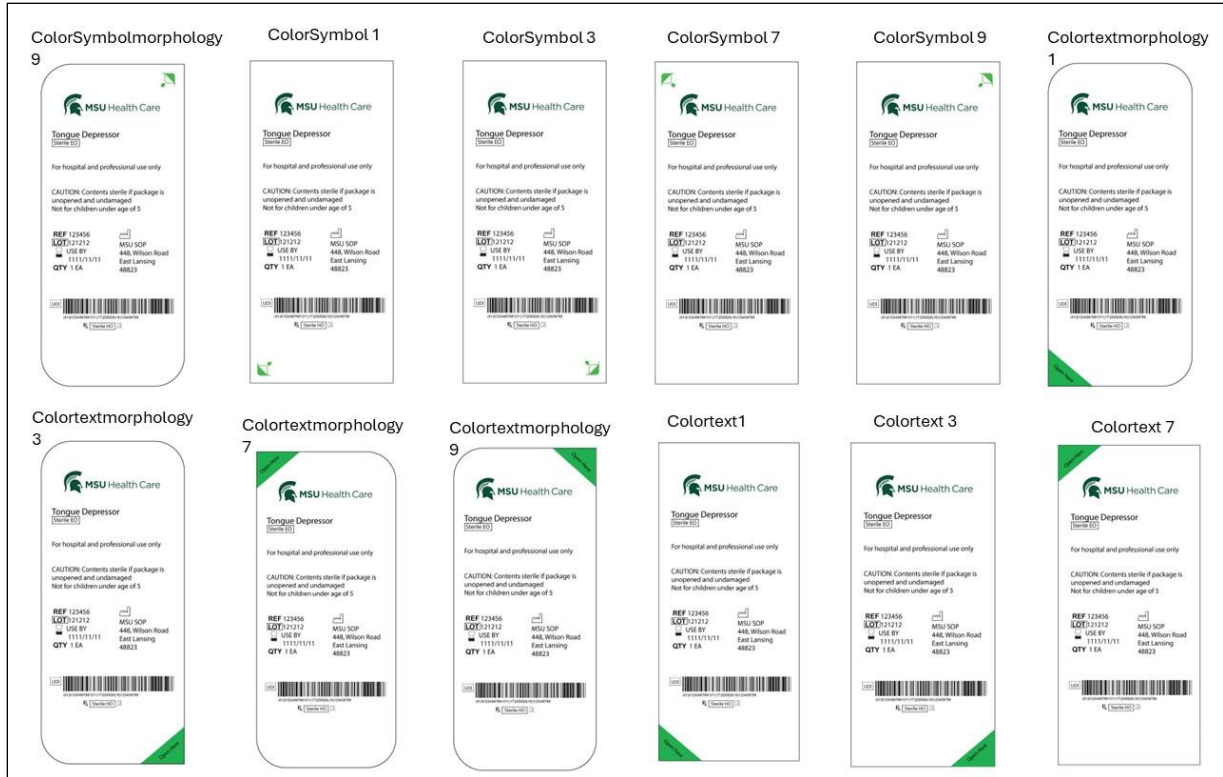


Figure B3: Part 2 of design cues on the four locations of peel pouch.

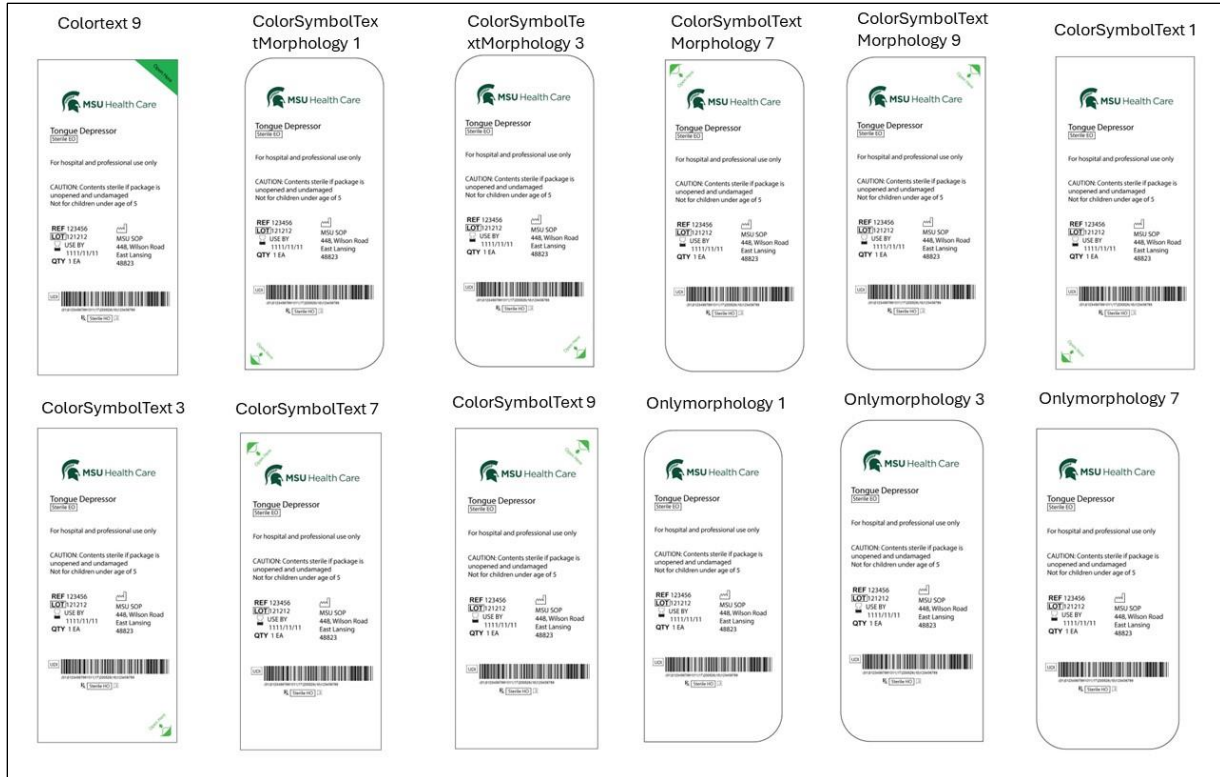


Figure B4: Part 3 of design cues on the four locations of peel pouch.

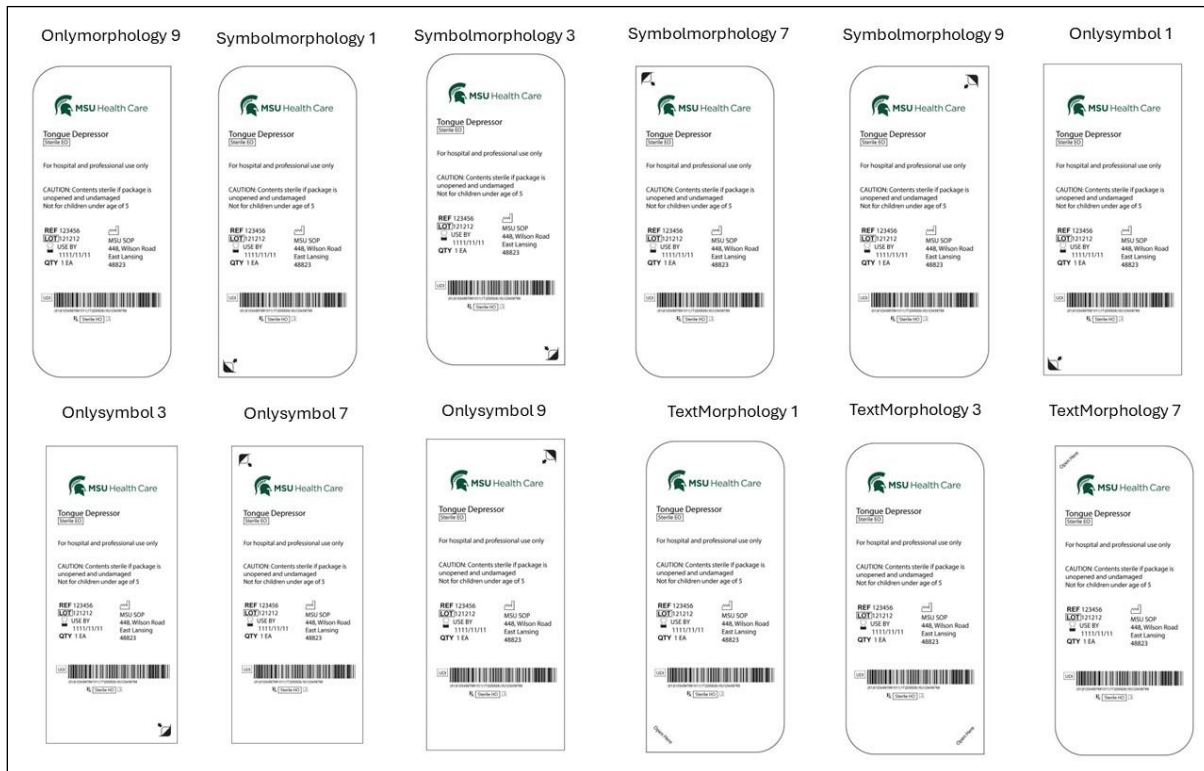


Figure B5: Part 4 of design cues on the four locations of peel pouch.

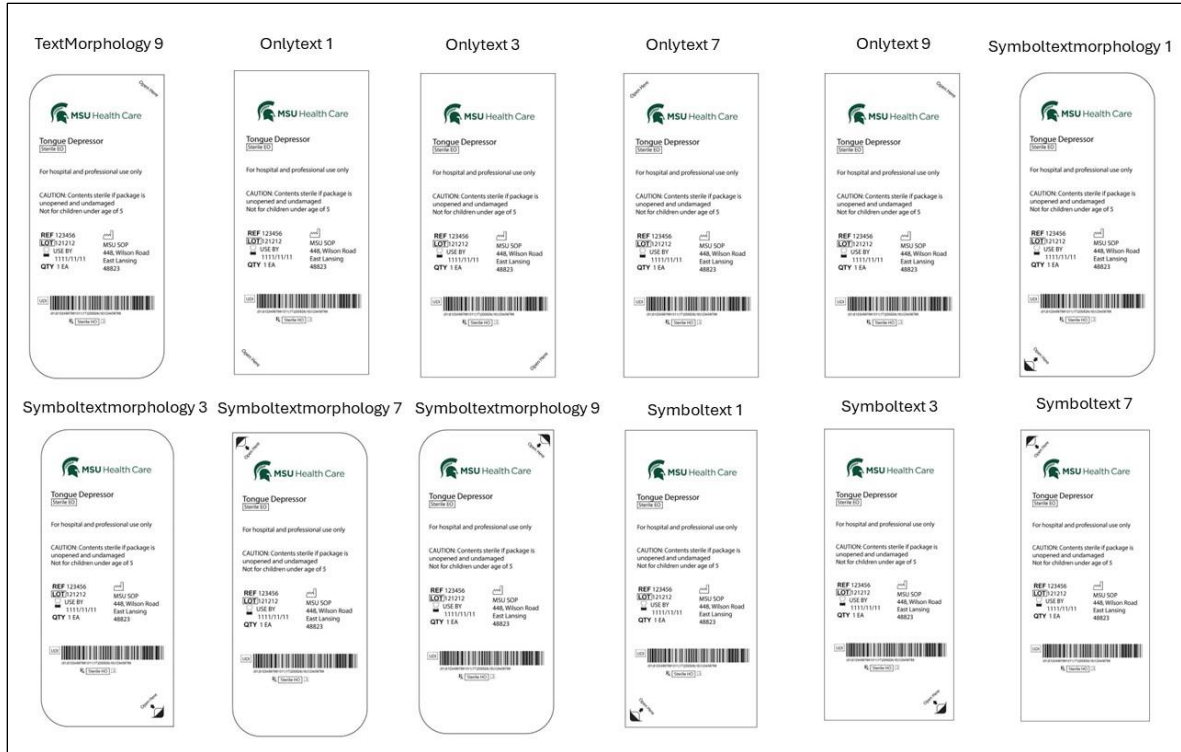


Figure B6: Part 5 of design cues on the four locations of peel pouch.



Figure B7: Part 6 of design cues on the four locations of peel pouch.

B.3. Tear Pouch Image Files

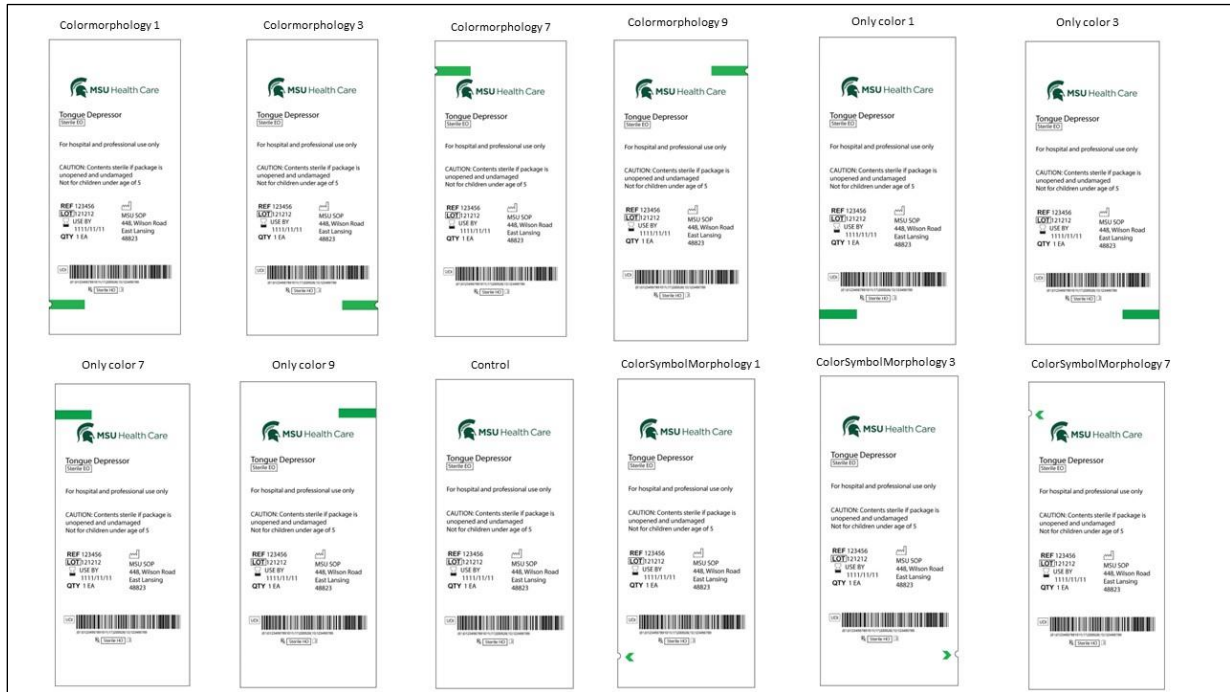


Figure B8: Part 1 of design cues on the four locations of tear pouch.

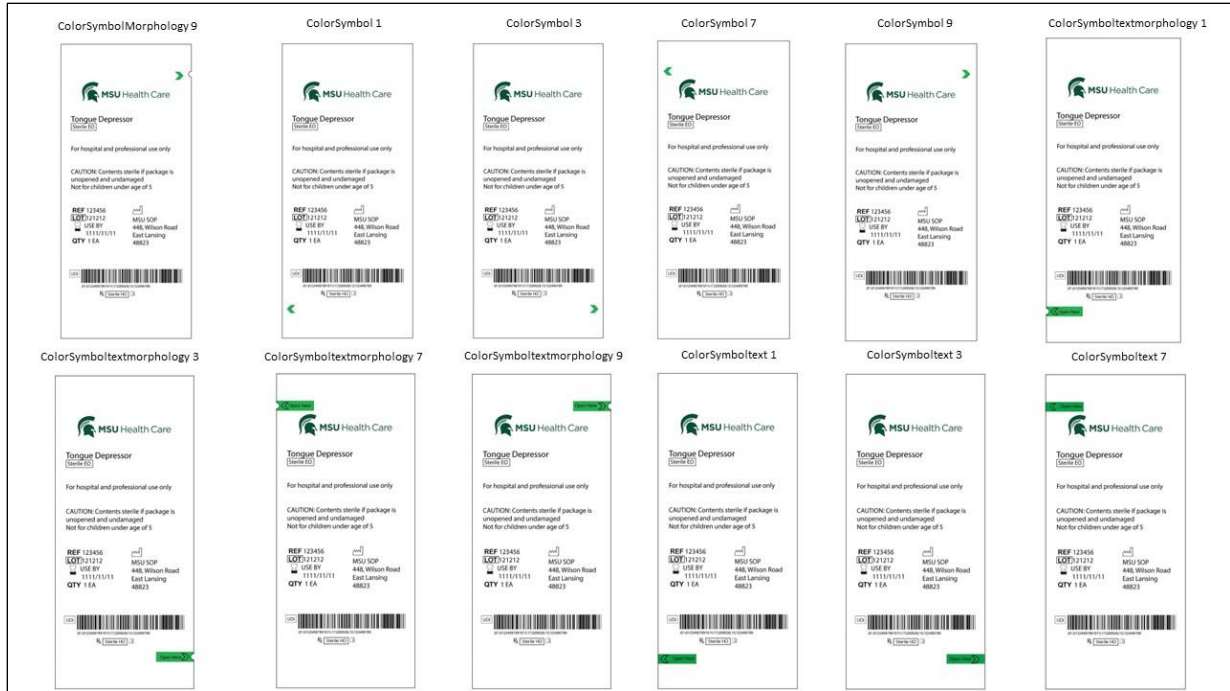


Figure B9: Part 2 of design cues on the four locations of tear pouch.

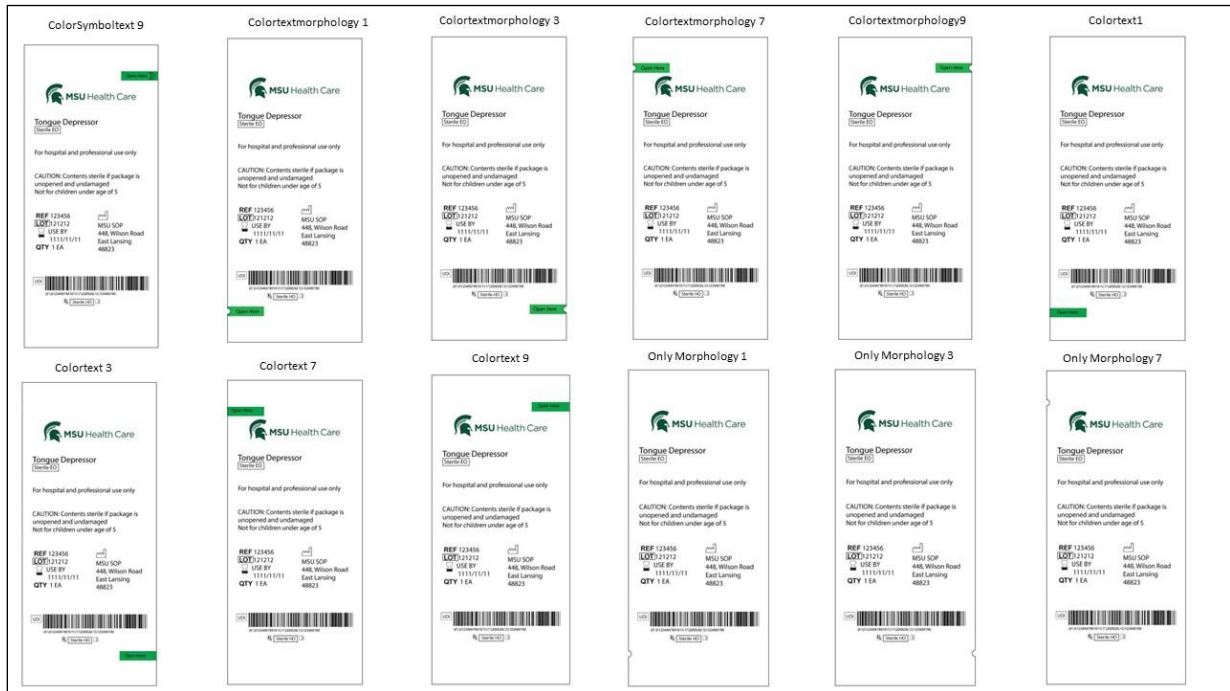


Figure B10: Part 3 of design cues on the four locations of tear pouch.

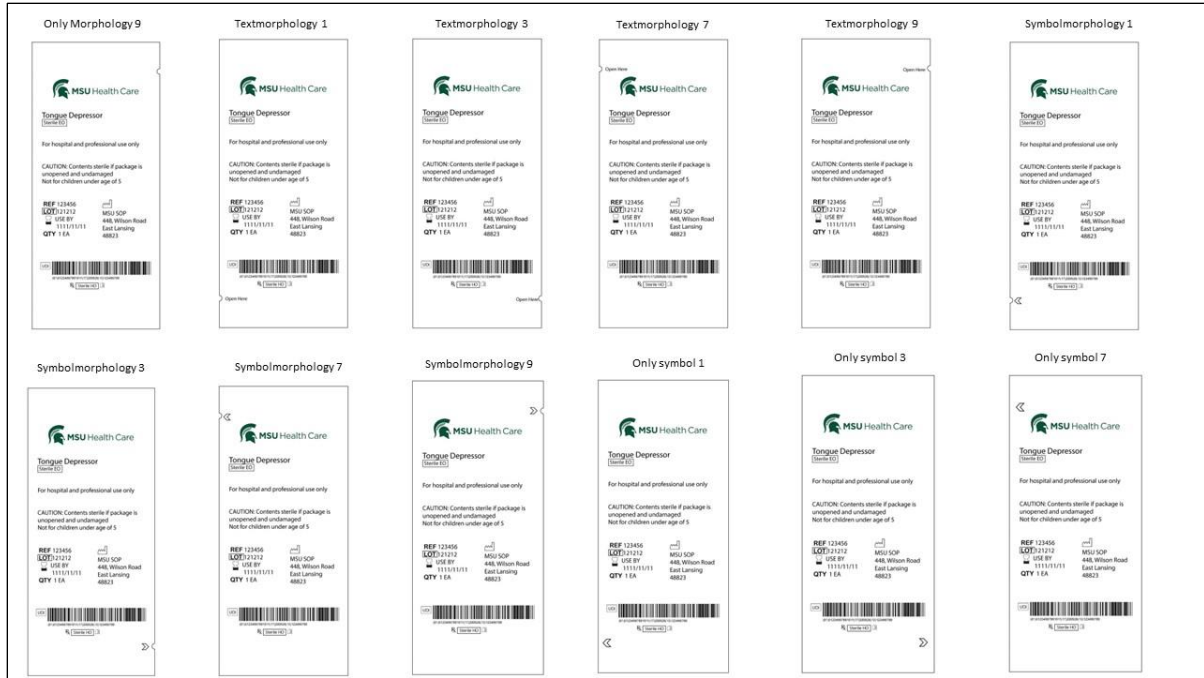


Figure B11: Part 4 of design cues on the four locations of tear pouch.

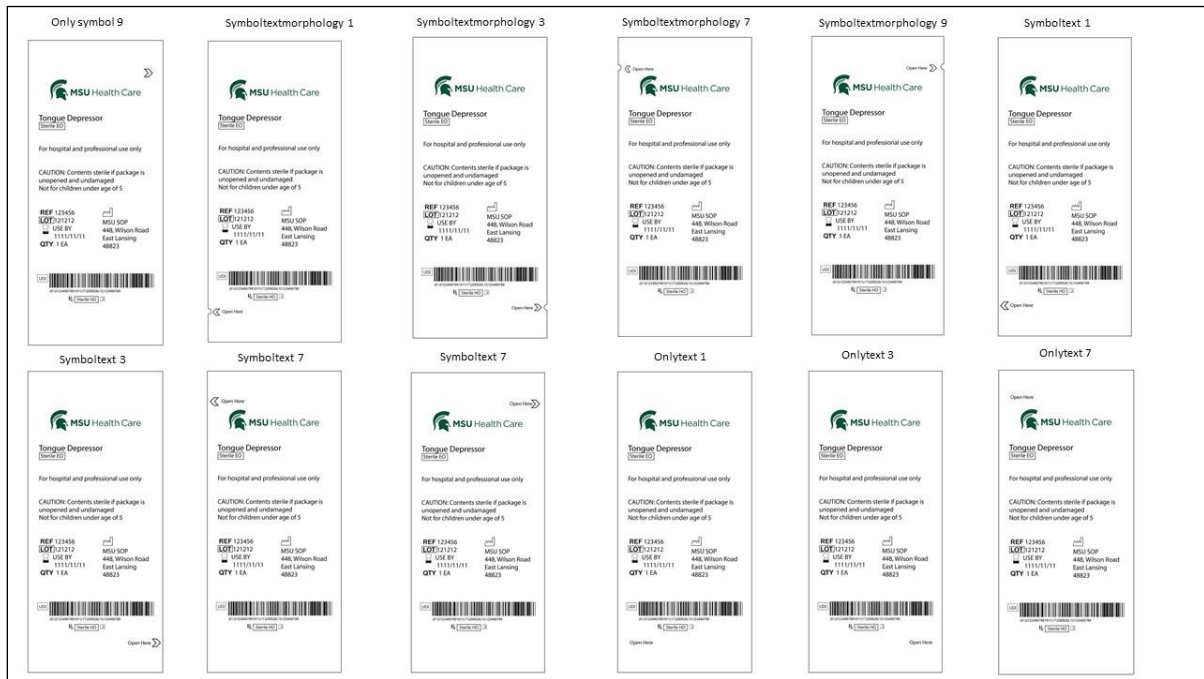


Figure B12: Part 5 of design cues on the four locations of tear pouch.



Figure B13: Part 6 of design cues on the four locations of tear pouch.

B.4. Thermoform Tray Image Files

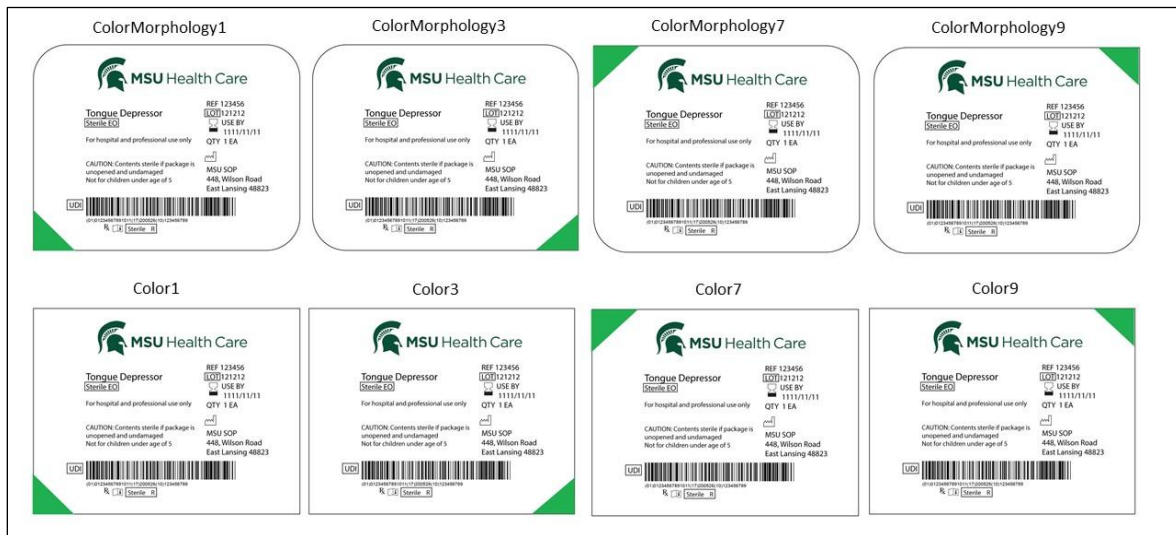


Figure B14: Part 1 of design cues on the four locations of thermoform tray.

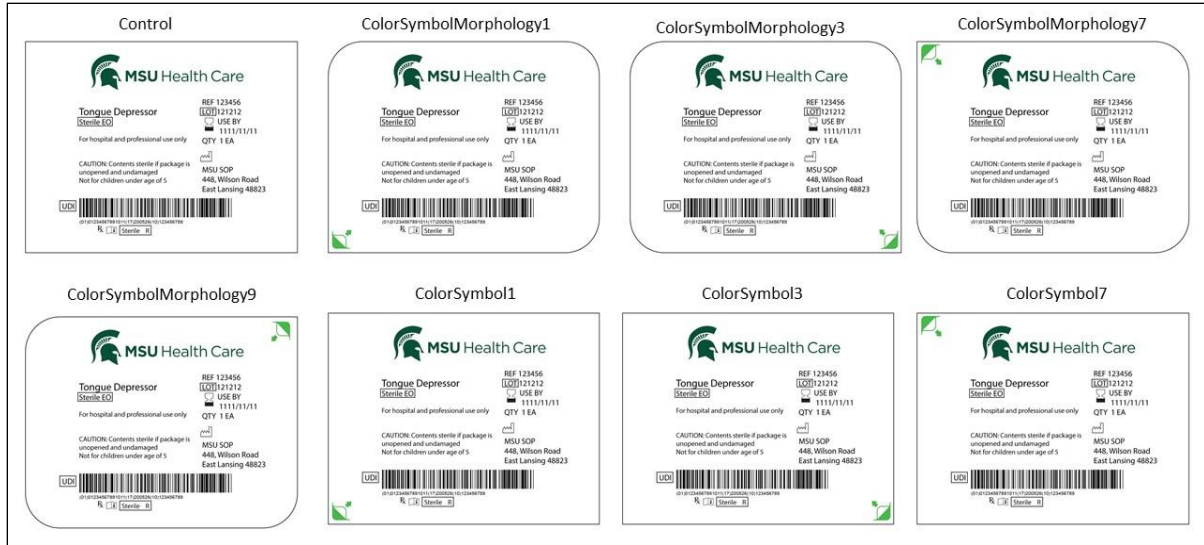


Figure B15: Part 2 of design cues on the four locations of thermoform tray.



Figure B16: Part 3 of design cues on the four locations of thermoform tray.

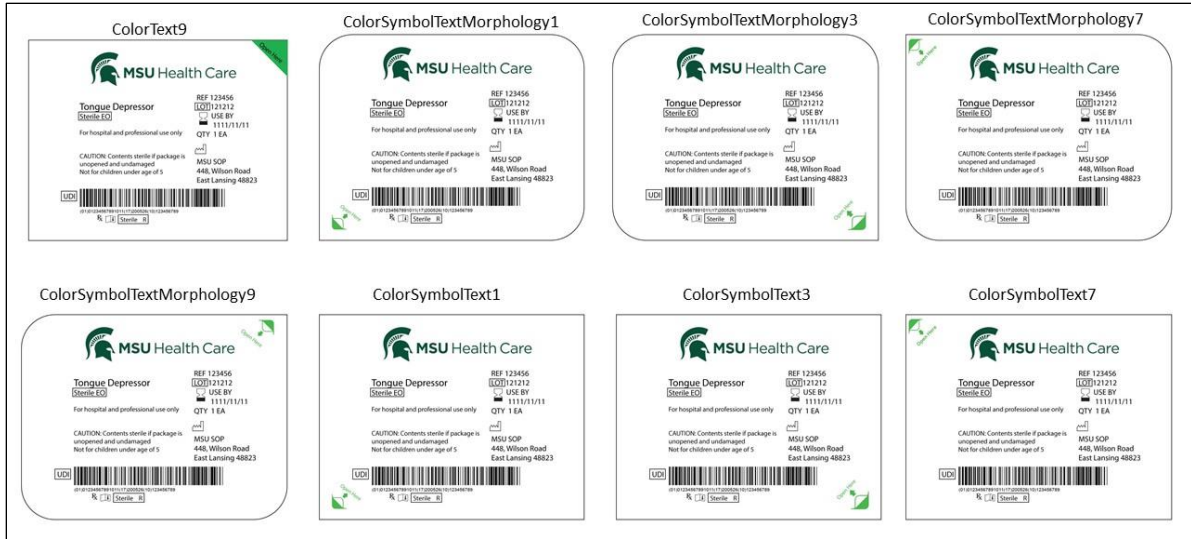


Figure B17: Part 4 of design cues on the four locations of thermoform tray.

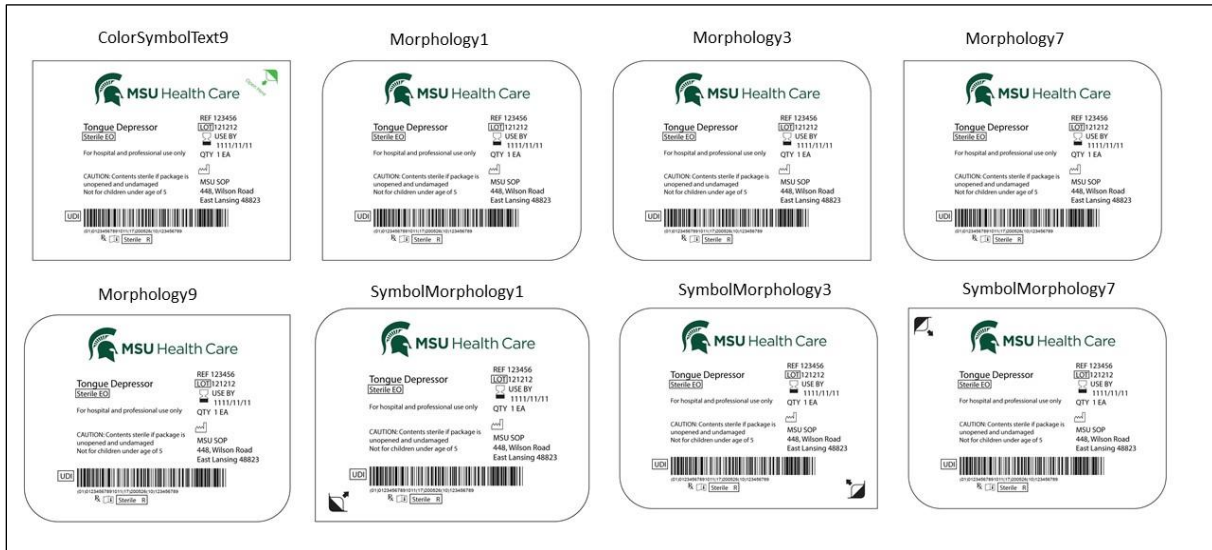


Figure B18: Part 5 of design cues on the four locations of thermoform tray.

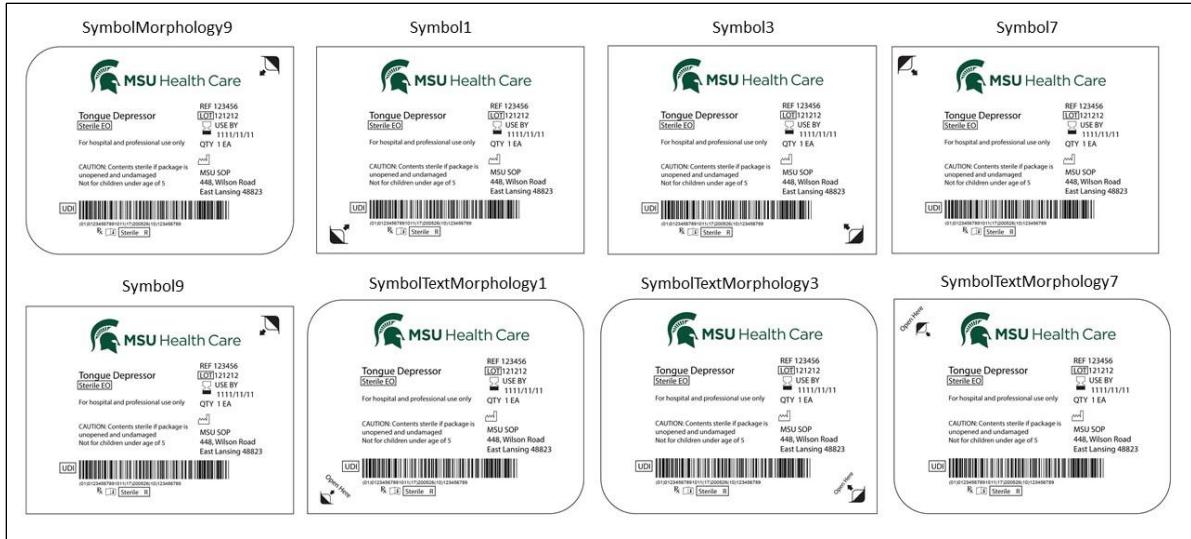


Figure B19: Part 6 of design cues on the four locations of thermoform tray.

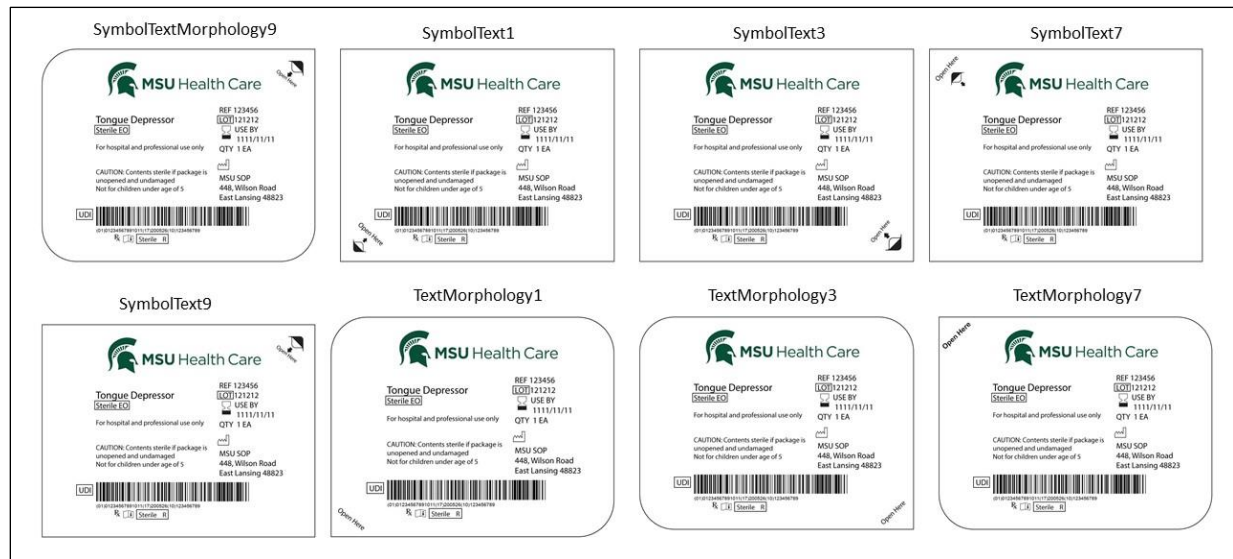


Figure B20: Part 7 of design cues on the four locations of thermoform tray.

APPENDIX C: INTERACTION BETWEEN TWO DESIGN CUES

Analysis to help understand the significant interaction term was further granulated by making comparisons between two of the four design cues. The reported results collapsed as averages over package type, and location. Confidence level of 95% has been adjusted using the Bonferroni method for two estimates with $\alpha=0.05$. The values have been back transformed to the original scale for presentation.

C.1.1 Color x Symbol

Table 1 and 2 explore the interaction between two design cues: color and symbol and the resultant time to correct response.

Table 1 and figure 1 suggest when symbol is absent (symbol=no) the presence of color results in significantly reduced time to correct response (1.18 seconds; SE 0.045; $p<0.0001$) than color no (1.93 seconds; SE 0.0741; $p<0.0001$).

The presence of both symbol (symbol=yes) and color (color_yes) result in quicker time to correct response (LSM 1.14 seconds; SE 0.0434 seconds; $p=0.0142$) than when the color is absent (color_no) when symbol is present (symbol=yes) (LSM 1.19 seconds; SE 0.0454 seconds; $p=0.0142$).

Table C1: Statistical analysis of the influence of color on the two levels of symbol across package type, text, morphology performed on log scale at 95% confidence level at $\alpha=0.05$ and their respective p values.

Symbol= No							
Color	LSM Response	SE	df	Lower CL	Upper CL	Group	p-value
Color_yes	1.18	0.045	63.9	1.08	1.29	a	<0.0001
Color_no	1.93	0.0741	66.1	1.77	2.11	b	<0.0001
Symbol= Yes							
Color	LSM Response	SE	df	Lower CL	Upper CL	Group	p-value
Color_yes	1.14	0.0434	63.8	1.04	1.24	a	0.0142
Color_no	1.19	0.0454	63.9	1.09	1.3	b	0.0142

Similarly, for the table 2 below we can interpret that presence of symbol (symbol_yes) helped reduce the time to correct response when color was absent (color=no) (LSM 1.19 seconds; SE 0.0454 seconds; $p<0.0001$) compared to color=No, symbol_no (LSM 1.93 seconds; SE 0.0741 seconds; $p<0.0001$). Refer figure 1.

Trails that included both color and symbol resulted in a reduced time to correct response (LSM 1.14 seconds; SE 0.0434 seconds) compared to the trails that included color but were absent symbols (color=yes, symbol_no) (LSM 1.18 seconds; SE 0.045 seconds; $p=0.0489$). Refer table 2.

Table C2: Statistical analysis of the influence of symbol on the two levels of color across package type, text, morphology performed on log scale at 95% confidence level at $\alpha=0.05$.

Color= No							
Symbol	LSM Time to correct Response Time	SE	df	Lower CL	Upper CL	Group	p-value
Symbol_yes	1.19	0.0454	63.9	1.09	1.3	a	<0.0001
Symbol_No	1.93	0.0741	66.1	1.77	2.11	b	<0.0001
Color= Yes							
Color	LSM Time to correct r response Time	SE	df	Lower CL	Upper CL	Group	p-value
Symbol_yes	1.14	0.0434	63.8	1.04	1.24	a	0.0489
Symbol_No	1.18	0.045	63.9	1.08	1.29	b	0.0489

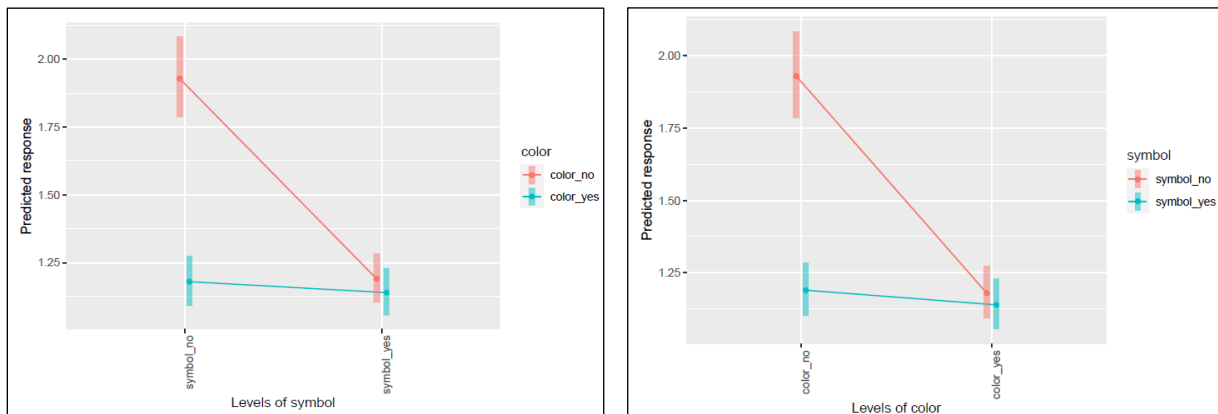


Figure C1: Graph plot describing the interaction between color and symbol, each at two levels (presence and absence) with respect to the time to correct response in seconds).

C.1.2 Color x Text

With reference to table 3 and figure 2, when trails with and without color are compared when text is absent, color trails induce a significantly lower response time compared to those without (respectively LSM 1.22 seconds; SE 0.464 vs 1.87 seconds; SE 0.072 seconds; $p<0.0001$).

When trails that do contain text are compared, this same relationship holds, specifically, the presence of color and text enables quicker and accurate identification of opening feature (LSM 1.1 seconds; SE 0.0421 seconds) compared those with text but no color (LSM 1.23 seconds; SE 0.0467 seconds). Refer table 3.

Table C3: Statistical analysis of the influence of color on the two levels of text across package type and location performed on log scale at 95% confidence level at $\alpha=0.05$.

Text= No							
Color	LSM Time to correct response	SE	df	Lower CL	Upper CL	Group	p-value
Color_yes	1.22	0.0464	63.9	1.12	1.33	a	<0.0001
Color_no	1.87	0.072	66.2	1.71	2.05	b	<0.0001
Text= Yes							
Color	LSM Time to correct response	SE	df	Lower CL	Upper CL	Group	p-value
Color_yes	1.1	0.0421	63.8	1.01	1.2	a	<0.0001
Color_no	1.23	0.0467	63.8	1.12	1.34	b	<0.0001

Similar patterns can be observed when we compare the levels of text with the presence and absence of color. The presence of at least text (color= no, text_yes) enables quicker time to correct response (LSM 1.23 seconds; SE 0.0467 seconds; $p<0.0001$). The absence of both color and text (color=no, text_no) results in higher time to correct response (LSM 1.87 seconds; SE 0.072 seconds; $p<0.0001$). Refer table 4.

The presence of color and text (color=yes, text_yes) result in quicker time to correct selection of responses (LSM 1.1 seconds; SE 0.0421 seconds; $p<0.0001$) as compared to when text is absent (text_no) (LSM 1.22 seconds; SE 0.0421 seconds; $p<0.0001$). Refer table 4.

Table C4: Statistical analysis of the influence of text on the two levels of color across package type, text, morphology performed on log scale at 95% confidence level at $\alpha=0.05$.

Color= No							
Text	LSM Time to correct response Time	SE	df	Lower CL	Upper CL	Group	
Text_yes	1.23	0.0467	63.8	1.12	1.34	a	<0.0001
Text_no	1.87	0.072	66.2	1.71	2.05	b	<0.0001
Color= Yes							
Text	LSM Time to correct response Time	SE	df	Lower CL	Upper CL	Group	
Text_yes	1.1	0.0421	63.8	1.01	1.2	a	<0.0001
Text_no	1.22	0.0464	63.9	1.12	1.33	b	<0.0001

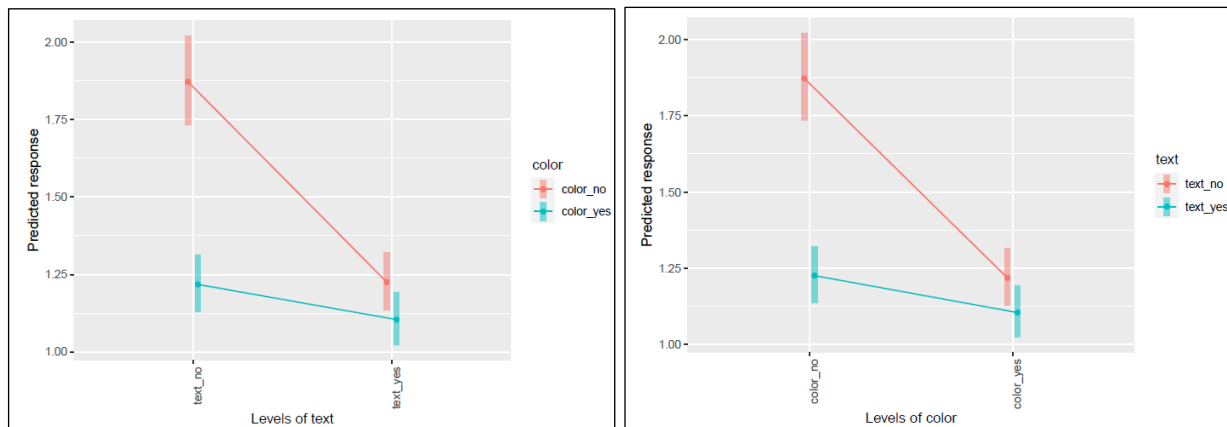


Figure C2: Graph plot describing the interaction between text and color, each at two levels (presence and absence) with respect to the time to correct response in seconds).

C.1.3 Color x Morphology

Table 5, table 6 and Figure 6 make comparisons of trials which examine the effects of morphology and color in combination. In trials where both color and morphology were absent (morphology=no, color_no), a higher time to correct response was observed (LSM 1.59 seconds; SE 0.0605 seconds; $p<0.0001$) as compared to trials where color was present (color_yes) and morphology absent (morphology=no) (LSM 1.18 seconds; SE 0.045 seconds; $p<0.0001$).

For trials where package morphology was changed (morphology=yes), the presence of color (color_yes) resulted in quicker time to correct response (LSM 1.14 seconds; SE 0.0434; $p < 0.0001$) than when color is absent (color_no) (LSM 1.44 seconds; SE 0.0555; $P < 0.0001$). See table 5.

Table C5: Statistical analysis of the influence of color on the two levels of morphology across package type, text, morphology performed on log scale at 95% confidence level at $\alpha=0.05$.

Morphology= no							
Color	LSM Time to correct response	SE	df	Lower CL	Upper CL	Group	p-value
Color_yes	1.18	0.045	63.9	1.08	1.29	a	<0.0001
Color_no	1.59	0.0605	63.9	1.46	1.73	b	<0.0001
Morphology= yes							
Color	LSM Time to correct response	SE	df	Lower CL	Upper CL	Group	p-value
Color_yes	1.14	0.0434	63.8	1.04	1.24	a	<0.0001
Color_no	1.44	0.0555	66.1	1.32	1.58	b	<0.0001

Table 6 explores the interaction of morphology and color. When trials with color absent and morphology present were compared with times that resulted from trials with color and morphology absent, a significant reduction in time to correct response was noted ($p < 0.0001$. Specifically, trials that had the morphology, but not color resulted in a LSM 1.44 seconds; SE 0.0555 seconds;) compared to an LSM 1.59 seconds; SE 0.0605 seconds for trials with both color and morphology absent.

The presence of color speeds up the time to correct response when color (color=yes), morphology (morphology_yes) are present (LSM 1.14 seconds; SE 0.0434 seconds; $p=0.0476$). The absence of morphology (morphology_no) when color is present (color=yes) increases the time to correct response significantly compared to color=yes, morphology_no ($p < 0.0001$) (LSM 1.18 seconds; SE 0.045 seconds; $p=0.0476$) Refer table 6.

Table C6: Statistical analysis of the influence of morphology on the two levels of color across package type, text, morphology performed on log scale at 95% confidence level at $\alpha=0.05$.

Color= No							
Morphology	LSM Time to correct response Time	SE	df	Lower CL	Upper CL	Group	p-value
Morphology_yes	1.44	0.0555	66.1	1.32	1.58	a	<0.0001
Morphology_no	1.59	0.0605	63.9	1.46	1.73	b	<0.0001
Color= Yes							
Morphology	LSM Time to correct response Time	SE	df	Lower CL	Upper CL	Group	p-value
Morphology_yes	1.14	0.0434	63.8	1.04	1.24	a	0.0476
Morphology_no	1.18	0.045	63.9	1.08	1.29	b	0.0476

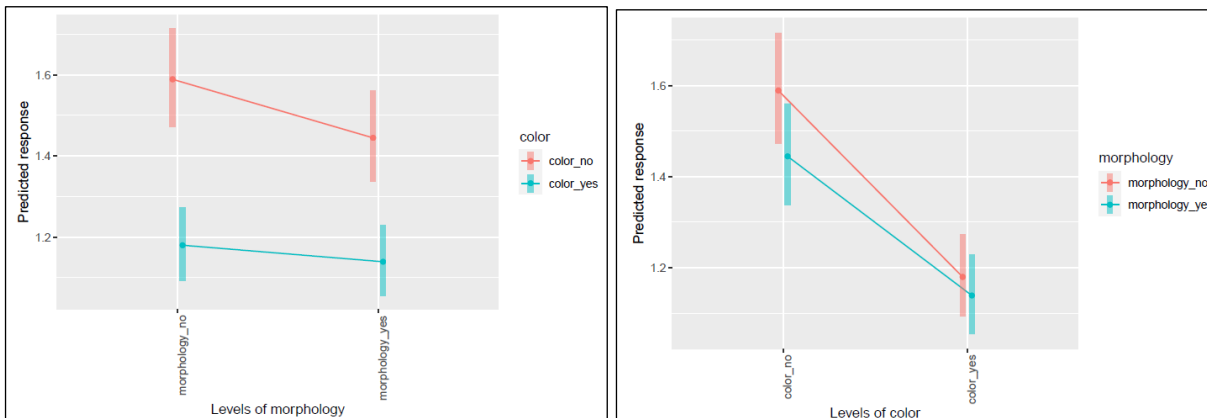


Figure C3: Graph plot describing the interaction between morphology and color, each at two levels (presence and absence) with respect to the time to correct response in seconds).

C.1.4 Symbol x Text

When text is absent (text=no), the presence of symbol contributes to quicker time to correct response (LSM 1.18 seconds; SE 0.045 seconds; $p<0.000$) compared to the absence of both text

and symbol (text=no, symbol_no) (LSM 1.93 seconds; SE 0.0743; $p < 0.0001$). Refer table 7 and figure 3.

The presence (symbol_yes) or absence of symbol (symbol_no) shows no evidence of significant differences in text, since the time to correct response for both the trails falls into the same group of significance ($p = 0.1638$). See table C7.

Table C7: Statistical analysis of the influence of symbol on the two levels of text across package type, text, morphology performed on log scale at 95% confidence level at $\alpha = 0.05$.

Text= No							
Symbol	LSM Time to correct response	SE	df	Lower CL	Upper CL	Group	p-value
Symbol_yes	1.18	0.045	63.9	1.08	1.29	a	<0.0001
Symbol_no	1.93	0.0743	66.2	1.77	2.11	b	<0.0001
Text= Yes							
Symbol	LSM Time to correct r response	SE	df	Lower CL	Upper CL	Group	p-value
Symbol_yes	1.15	0.0438	63.8	1.05	1.25	a	0.1638
Symbol_no	1.18	0.0449	63.8	1.08	1.29	a	0.1638

8 compares the effect of text on the two levels of symbol. The presence of text (text_yes) significantly reduces the time to correct response (LSM 1.18 seconds; 0.0449 seconds; $p < 0.0001$) when symbol is absent (symbol=no), whereas when both symbol and text are absent (symbol=no, text_yes) the time to correct response goes up (LSM 1.93 seconds; 0.0743 seconds; $p < 0.0001$).

The response pattern in table 8 is like table 7, where it can be observed that the presence or absence of text shows no evidence of significant effect on the presence of symbol (symbol=yes), having their significance level categorized into the same group ($p = 0.1271$). Refer figure 4 for a graphical representation.

Table C8: Statistical analysis of the influence of morphology on the two levels of color across package type, text, morphology performed on log scale at 95% confidence level at $\alpha=0.05$.

Symbol=no							
Text	LSM Time to correct response	SE	df	Lower CL	Upper CL	Group	p-value
Text_yes	1.18	0.0449	63.8	1.08	1.29	a	<0.0001
Text_no	1.93	0.0743	66.2	1.77	2.11	b	<0.0001
Symbol=yes							
Text	LSM Time to correct response	SE	df	Lower CL	Upper CL	Group	p-value
Text_yes	1.15	0.0438	63.8	1.05	1.25	a	0.1271
Text_no	1.18	0.045	63.9	1.08	1.29	a	0.1271

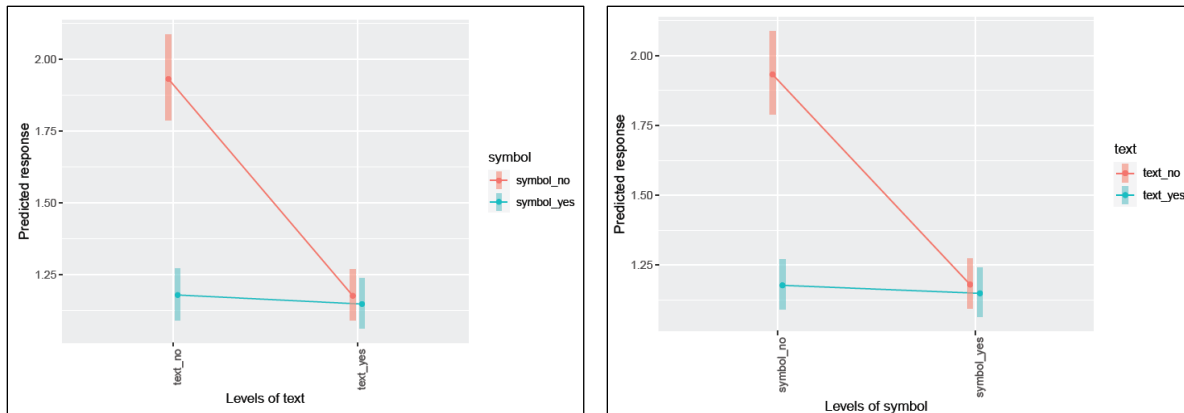


Figure C4: Graph plot describing the interaction between text and symbol, each at two levels (presence and absence) with respect to the time to correct response in seconds).

C.1.5 Symbol x Morphology

Table 9 and figure 5.24 show the influence of symbol in the time to correct response on the two levels (morphology=no, morphology=yes). Symbol presence (symbol_yes) enabled quicker time to correct response (LSM 1.18 seconds; SE 0.0448 seconds; $p<0.0001$) when morphology was absent (morphology=no) which is a significant difference when both morphology and symbol are absent (morphology=no, symbol_no) (LSM 1.59 seconds; SE 0.067 seconds; $p<0.0001$).

Symbol displayed significant effects in time to correct response with presence of morphology (morphology=yes). The combination of morphology=yes, symbol_yes reduced time to correct response (LSM 1.15 seconds; SE 0.0439 seconds; $p < 0.0001$). The absence of symbol (symbol_no) increased the time to correct response (LSM 1.43 seconds; SE 0.0549 seconds; $p < 0.0001$) even though morphology was present (morphology=yes). Refer table 9 and figure 5.

Table C9: Statistical analysis of the influence of symbol on the two levels of morphology across package type, text, morphology performed on log scale at 95% confidence level at $\alpha = 0.05$.

Morphology= no							
Symbol	LSM Time to correct response	SE	df	Lower CL	Upper CL	Group	p-value
Symbol_yes	1.18	0.0448	63.9	1.08	1.28	a	<0.0001
Symbol_no	1.59	0.0607	63.9	1.46	1.74	b	<0.0001
Morphology=yes							
Symbol	LSM Time to correct response	SE	df	Lower CL	Upper CL	Group	p-value
Symbol_yes	1.15	0.0439	63.8	1.06	1.26	a	<0.0001
Symbol_no	1.43	0.0549	66.1	1.31	1.56	b	<0.0001

The effects of morphology are compared with the two levels of symbol. When symbol is absent (symbol=no), but morphology is present morphology (morphology_yes), the time to correct response is reduced (LSM 1.43 seconds; 0.0549 seconds; $p < 0.0001$) compared to the absence of both, symbol (symbol=no), morphology (morphology_no) (LSM 1.59 seconds; SE 0.0607 seconds; $p < 0.0001$). Refer table 10 and figure 5.

The pattern is different when we observe the effect of morphology on the presence of symbol (symbol=yes). The presence or absence of morphology shows no evidence of significant difference on the presence of symbol (symbol= yes), having their time to correct response fall in the same level of significance ($p = 0.2349$). Refer table 10 and figure 5.

Table C10: Statistical analysis of the influence of morphology on the two levels of symbol across package type, text, morphology performed on log scale at 95% confidence level at $\alpha=0.05$.

Symbol=no							
Morphology	LSM Time to correct response	SE	df	Lower CL	Upper CL	Group	p-value
Morphology_yes	1.43	0.0549	66.1	1.31	1.56	a	<0.0001
Morphology_no	1.59	0.0607	63.9	1.46	1.74	b	<0.0001
Symbol=yes							
Morphology	LSM Time to correct response	SE	df	Lower CL	Upper CL	Group	p-value
Morphology_yes	1.15	0.0439	63.8	1.06	1.26	a	0.2349
Morphology_no	1.18	0.0448	63.9	1.08	1.28	a	0.2349

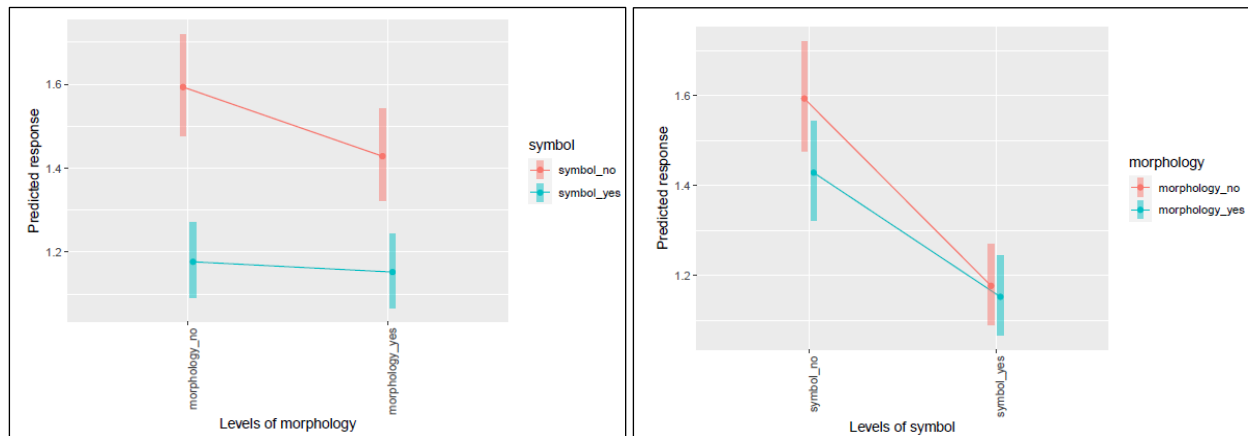


Figure C5: Graph plot describing the interaction between morphology and color, each at two levels (presence and absence) with respect to the time to correct response in seconds).

C.1.6 Text x Morphology

For the two levels of morphology, there is a significant difference in the time to correct response values when text is present and absent. Table 11 and figure 6 suggests presence of text (text_yes) when morphology is absent (morphology=no) reduces the time to correct response (LSM 1.18 seconds; SE 0.045 seconds; $p<0.0001$) than having both morphology and text absent (morphology=no, text_no) (LSM 1.59 seconds; SE 0.0605 seconds; $p<0.0001$).

The presence of morphology and text (morphology=yes, text_yes) bring down the time to correct response (LSM 1.15 seconds; SE 0.0437 seconds; $p < 0.0001$) compared to morphology=yes, text_no (LSM 1.44 seconds; SE 0.0552 seconds; $p < 0.0001$). Refer table 11 and figure 6.

Table C11: Statistical analysis of the influence of text on the two levels of morphology across package type, text, morphology performed on log scale at 95% confidence level at $\alpha = 0.05$.

Morphology=no							
Text	LSM Time to correct response	SE	df	Lower CL	Upper CL	Group	p-value
Text_yes	1.18	0.045	63.8	1.08	1.29	a	<0.0001
Text_no	1.59	0.0605	63.9	1.45	1.73	b	<0.0001
Morphology=yes							
Text	LSM Time to correct response	SE	df	Lower CL	Upper CL	Group	p-value
Text_yes	1.15	0.0437	63.8	1.05	1.25	a	<0.0001
Text_no	1.44	0.0552	66.1	1.32	1.57	b	<0.0001

Table 12 implies that time to correct response is different for text is absent (text=no) and morphology is present (morphology_yes) (LSM 1.44 seconds; 0.0552 seconds; $p < 0.0001$) than when morphology and text both are absent (morphology=no, text_no) (1.59 seconds; SE 0.0605 seconds; $p < 0.0001$).

Whereas the presence of text (text=yes) is independent of the presence or absence of morphology and shows no evidence of significant difference falling under same group of significance ($p = 0.0872$). Refer table 12 and figure 6.

Table C12: Statistical analysis of the influence of morphology on the two levels of text across package type, text, morphology performed on log scale at 95% confidence level at $\alpha=0.05$.

Text=no							
Morphology	LSM Time to correct Response	SE	df	Lower CL	Upper CL	Group	p-value
Morphology_yes	1.44	0.0552	66.1	1.32	1.57	a	<0.0001
Morphology_no	1.59	0.0605	63.9	1.45	1.73	b	<0.0001
Text=yes							
Morphology	LSM Time to correct Response	SE	df	Lower CL	Upper CL	Group	p-value
Morphology_yes	1.15	0.0437	63.8	1.05	1.25	a	0.0872
Morphology_no	1.18	0.045	63.8	1.08	1.29	a	0.0872

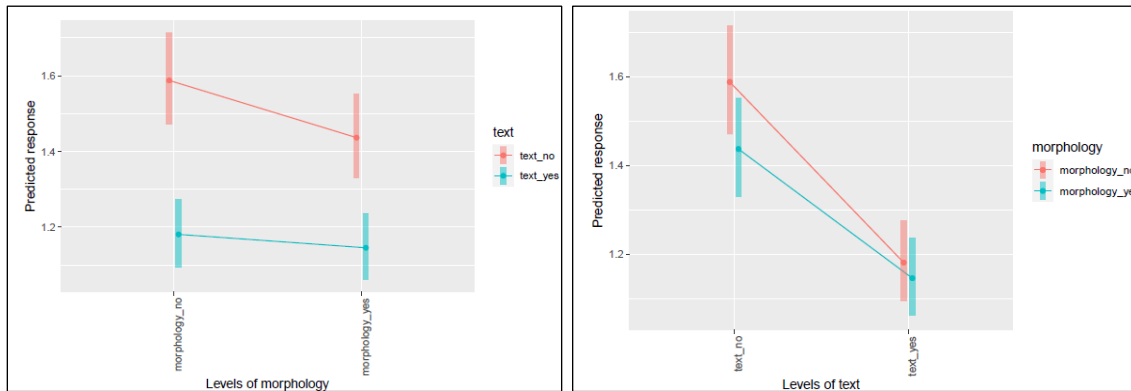


Figure C6: Graph plot describing the interaction between morphology and text, each at two levels (presence and absence) with respect to the time to correct response in seconds).