SMART TOYS FOR SENSING AND SOOTHING DISTRESS IN PEDIATRIC PATIENTS

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Abstract

This thesis develops and evaluates child-centered technologies to support remote monitoring of pediatric patients, with an emphasis on childhood cancer and pediatric chronic pain. For these and many other health conditions, current therapies tend to focus on treating physical symptoms yet neglect the psycho-emotional aspects of managing the illness. However, such mental states play a major role in recovery. Research has shown that cancer patients with better mental health have better prognoses, higher possibilities of remission, and faster healing processes, while chronic pain patients with better mental health report lower levels of pain.

To enable more personalized, continuous, and scalable monitoring of emotional status and distress in pediatric patients, this thesis works to develop an affordable, acceptable sensor device with a toy-based form factor that can be deployed in both clinical and home settings to augment care. Specifically, we report on the design, implementation, and evaluation of prototypes that integrate sensors for assessing markers of distress related to heart rate, oximetry, and movement.

Results indicate that these sensor signals are useful emotional measures for therapists and families and that the toy-based design appeals to children, promotes playful engagement, and scores very high on measures of enjoyment and likeability. Preliminary findings related to the potential for the toy to deliver adaptive interventions and/or therapeutic support indicate an improvement in overall mood after half an hour of playing with the device. Future steps include optimizing the microcontroller functions, creating machine learning algorithms to predict behavioral patterns, and improving therapeutic components (e.g., soothing) and just-in-time support. Overall, this project lays the foundations for future

technological enhancements at the intersection of healthcare technology and therapeutic play.

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1. Introduction

1.1 Motivation

Tracking the emotional well-being and mental health of children dealing with medical issues is a vital yet sometimes challenging part of pediatric healthcare services. Various monitoring methods rely on occasional clinic visits which may fail to capture the child's ongoing emotional state and overall well-being in a comprehensive manner. Emotional wellness plays a role in overall health and affects the progress of different pediatric conditions; however, it tends to be overlooked when compared to physical symptoms.

The study studies two specific populations of children: ones suffering from cancer and those with chronic pain as these situations showcase the interplay, between physical ailments and mental well-being as well as the gaps that exist in monitoring the latter. These specific conditions were selected as they underscore the difficulties in monitoring the emotional health of children undergoing treatment. For instance, as of 2021, there are over 1.9 million newly diagnosed cancer cases in the US, with nearly 20,000 of them being children under 15. Approximately 1 in every 285 American children will be diagnosed with cancer before they reach the age of 20 [1]. Additionally, it is estimated that approximately 20,000 to 30,000 children in the US have cancer, with 40% of these children suffering from mental health issues, constituting roughly 8,000 to 12,000 children [2]. Furthermore, around 20% of all children in the US suffer from chronic pain, and approximately 30% of these children suffer from some kind of mental health condition (roughly 2.25 million) [3].

These statistics highlight the significant burden of pediatric cancer and chronic pain, underscoring the need for enhanced emotional support.

The inspiration behind this research stems from the necessity to enhance support and continuous monitoring for young patients using an affordable and user-centered solution. Throughout the thesis, we show the connection of illnesses with mental health and emotional well-being as well as some examples of how HealPet works, occasionally referring to the aforementioned conditions. Research has shown that cancer patients with better mental health have better prognoses, higher possibilities of remission, and faster healing processes [4]. Similarly, chronic pain patients with better mental health report lower levels of pain [5]. Creating a toy companion, which I refer to as the HealPet (Health and Emotional Assistance for Little ones through Plush Education and Therapy)—for monitoring aims to fill this void by offering a fun and interactive way to monitor and aid in children's well-being. By encouraging play and providing insights into a child's emotions, this approach has the potential to significantly boost the wellness and happiness of patients, serving as a caring addition to conventional treatments. This project is primarily aimed at ill children aged 2-9, but a future goal is to evaluate and personalize the toy's suitability for different kinds of pediatric patients starting with cancer and chronic pain.

This research aims to bridge the divide between emotional care and physical care, propelling progress in pediatric support. The thesis explores the creation, testing, and evaluation of an affordable toy monitoring companion aimed at improving emotional support for pediatric patients. The ultimate goal is to create a personalized, continuous, and scalable monitoring system that can be deployed in both clinical and home settings to augment care.

1.1.1 Research Questions

To better frame our research motivation and overall aim we defined some research questions as follows:

- How can a smart toy like HealPet effectively monitor emotional distress in children?
- What kind of sensors are the most reliable indicators of emotional distress in pediatric patients?
- Can real-time emotional support from smart toys impact the overall mood and mental health of children during anxiety or distress moments?
- What are the most significant challenges in balancing affordability and functionality when designing sensor-integrated toys for pediatric health monitoring?
- How do pediatric patients and their families perceive the emotional and therapeutic impact of toy-based health monitoring systems in clinical and home settings?
- How do parents and clinicians perceive the usability and effectiveness of HealPet as an emotional monitoring and support tool for pediatric patients?

1.2 Scope of the Thesis

This thesis explores the creation, testing, and evaluation of an affordable, toy monitoring companion aimed at improving emotional support for pediatric children. It covers:

- The theoretical foundations of the emotional impact of pediatric health conditions and the significance of mental health in recovery and prognosis of such conditions.

- The design and development process of the toy, including the hardware components, user interface, and integration of the monitoring system.
- Testing and validating the toy's effectiveness through surveys and experiments, comparing its impact on children’s mood and emotional well-being against traditional methods.
- Analysis of the constraints, challenges, and potential enhancements, such as optimizing microcontroller functions and improving the toy's soothing components.
- Reflection on the constraints and obstacles encountered over the course of the study, and potential opportunities for future work.

1.3 Thesis Outline

This thesis emphasizes the role that interactive toys play in promoting well-being and monitoring emotions. It starts by discussing the aspects of children's play and the process of advancement and provides a thorough statistical analysis showcasing the importance of this innovative technology. The thesis then explores the theoretical groundwork guiding research paths particularly focusing on utilizing toy designs and monitoring metrics, like heart rate and respiration rate. It further elaborates on how the study is integrated into the Arduino microcontroller framework detailing the systems design, implementation, and operational procedures for physiological measurements. Subsequently, it delves into the calming effects and user-centric design elements. The structure of this thesis aims to lead readers through each stage of technology evolution, from concept development to deployment of a monitoring tool, while examining broader implications in biomedical engineering and healthcare.

2. Background

2.1 Child Emotion and Mental Health

Children's emotional well-being and mental health are closely intertwined, with each affecting the other. Various factors, like genetics, environment, family background, and adverse life events, can all contribute to shaping the health challenges faced by children. If left unaddressed, these issues can develop into long-term struggles with health and trauma.

The range of emotional and mental health issues in children varies from minor concerns to severe conditions such as anxiety, depression, ADHD, and behavioral issues. It is essential for a child's growth and overall well-being that these challenges are acknowledged and addressed. To enable timely intervention, parents and caregivers must stay vigilant for changes in a child's behavior, mood, or daily routines.

Studies indicate that children's emotional well-being and growth heavily depend on their emotions and mental states. Teaching children how to manage their emotions helps them effectively handle stress and engage positively with others. This ability is critical because children experience an array of emotions, from joy and sadness to anger, fear, and love [6].These feelings can be overwhelming if children struggle to express themselves. Children can handle stress better by mastering regulation, fostering positive connections with others, and cultivating meaningful relationships [7].

From an early age, children observe the behavior of those around them. That is why parents, caregivers, and teachers must help children learn how to manage their emotions. For instance, parents and caregivers can assist children in identifying and labeling their feelings by generally discussing emotions with them, asking them personally how they are doing emotionally, and encouraging them to express themselves. They can also teach strategies like breathing, taking breaks when needed, or seeking help from others. Moreover, creating an environment where children feel secure is crucial. The key is establishing routines, reducing exposure to stressors, and providing opportunities for children to engage in activities such as physical exercise that promote emotional well-being. This research will explore the impact of children's emotions on their well-being while underscoring the importance of regulation and introducing a range of intelligent toys designed to monitor children's emotional states.

2.1.1 Challenges of Tracking Emotions and Mental Health in Children

Recognizing emotions is among the abilities that develop and become noticeable in early childhood, typically around 4 to 7 months. From a perspective, being able to interpret someone's emotional state holds significant value as it helps us adjust our behavior in social settings. While managing emotions can be challenging for adults, it is significantly more complex for young children with developing brains. They are learning to recognize negative emotions within themselves and others and then identifying appropriate responses to these feelings. For individuals who have experienced abuse, endured pain, faced poverty, or dealt with disabilities, the learning curve can be particularly steep. Young children’s limited self-awareness and ability to express themselves creates gaps in how data is gathered.

Comprehending the impact of emotion on the body is a difficult task for researchers. It requires methods that monitor changes in heart rate, electrodermal response, and pathway activation. This study will examine records related to speech analysis, self-reported information, maternal recognition changes, expressions, and/or emotional shifts that can be consistently monitored and compared to address the challenges associated with collecting data for children.

This research aims to move beyond approaches of identification, understanding, classification, and emotional control that have traditionally been used to comprehend emotions in adults effectively. As evident from the lack of data, no new assessments adequately encompass the complexities of multidimensional emotional studies, highlighting the necessity for an analysis that establishes connections among variables, strategies, and techniques to facilitate a comprehensive and cohesive understanding, especially in children.

Consequently, one of the goals of this study is to outline some neurophysiological methodologies in current use and propose an innovative, broadly applicable approach to monitoring children's emotions.

2.1.2 Exploring Children's Emotions and Their Growth

Emotions are commonly described as coordinated responses involving mental and motivational components [8] representing pleasurable or displeasurable mental states [9]. These emotional experiences result from brain activity in areas like the amygdala, insula cingulate cortex, and orbitofrontal cortex [10]. Emotions shape children's behavior by influencing their thinking processes, learning abilities, and actions [11]. Therefore, understanding how to assess children's emotions can provide insights into their development.

Researchers like Ekman and Oster explored the origins and progression of emotions by observing expressions such as frowns and smiles in newborns using the Facial Action Coding System [12]. One of their most notable studies focused on categorizing each movement based on patterns to understand the expression of different emotions better. This was explored by how well people could recognize emotions after watching videos of an actor displaying anger, happiness, sadness, and a neutral expression while also making sounds that matched each emotion [13]. Participants were then asked to name the emotion expressed by the actor. Subsequently, they categorized the responses as positive (smiling, laughing), neutral (no expression, calm), or negative (whining, furrowing brows). The ability to identify emotions typically develops around 5 or 6 months of age [14]. Early research on children's reactions also delved into how changes in heart rate can provide insights into their emotional states. For instance, researchers monitored a group of children’s heart rates while watching films designed to evoke emotions. The findings revealed increased heart rates during anxiety-inducing scenes and decreased rates during those meant to evoke sadness [15], leading to the development of tests to assess children's well-being and emotional responses. Some standard methods used in these assessments include;

Self-Reporting Measures:

These measures are frequently employed to gauge children's experiences, attitudes, and overall well-being.

For example, the Strengths and Difficulties Questionnaire (SDQ), developed by Goodman (1997), examines behavioral issues [16], while the Child Depression Inventory

(CDI), developed by Kovacs in 1985, measures symptoms [17]. These tools provide insights into how children perceive themselves, helping to identify challenges early on. However, they may be influenced by factors like children's self-awareness, social desirability biases, and developmental considerations.

Observational Assessments:

Observational assessments involve observing children's behaviors in situations. The Ainsworth Strange Situation Procedure, introduced by Ainsworth and others in 1978, focuses on patterns [18], while the Eyberg Child Behavior Inventory (ECBI), created by Eyberg and Pincus in 1999, assesses problems [19]. These assessments offer insights into how children express their emotions and interact with others, assisting in evaluating those who find it challenging to communicate their feelings. Nonetheless, observer biases and context-specific differences can impact the results.

Clinical Interviews:

Clinical interviews consist of semi-structured discussions between clinicians and children. One diagnostic interview used to assess disorders in children is the Kiddie Schedule for Affective Disorders and Schizophrenia (K SADS), developed by Kaufman et al. in 1997 [20].

Clinical interviews provide insight into children's well-being by delving into their thoughts, feelings, and actions. However, they rely heavily on the child's willingness and ability to communicate effectively, and the interviewer's expertise can influence the quality of results.

Neuroimaging:

Advancements in neuroimaging techniques have transformed how we assess children's health and emotions. Functional MRI (fMRI) allows researchers to explore brain activity patterns linked to emotions and disorders. For example, a study done by Tottenham et al. utilized fMRI to investigate how children with anxiety disorders respond to faces. While neuroimaging helps uncover the mechanisms behind child health, it comes with challenges such as requiring specialized equipment, ethical considerations, and a potential lack of specificity due to brain development [21].

A child's mental health and emotions demand an assessment strategy. Psychological tests like self-reports, observations, clinical interviews, and neuroimaging collectively contribute to understanding a child's well-being. Researchers and practitioners need to weigh the strengths and limitations of each method when developing assessment protocols, intending to make diagnoses, provide tailored interventions, and enhance children's welfare.

In our research progress, we aim to create a holistic method for evaluating children's mental health. This approach will help us better recognize and provide assistance for wellness in children facing challenges during this crucial growth period.

2.2 Child's Play, Mental Health, and the Emotionally Developed Child

Engaging in play is crucial for growth, and it has long been acknowledged as such across different eras. From childhood through adolescence and into adulthood, play plays a role in shaping cognitive, social, and emotional development.

2.2.1 Cognitive Benefits of Play

Research has shown that play contributes to enhancing development in children. Various studies have revealed that play is linked to improved problem-solving abilities, creativity, and executive function [22,23]. For instance, one study found that preschoolers who participated in play demonstrated cognitive adaptability and control [24]. Another study highlighted that children who engaged more in recreational activities showed better working memory and attention skills [25]. These insights indicate that play fosters the advancement of skills necessary for academic achievement and overall well-being.

2.2.2 Social Benefits of Play

Engaging in playful activities also contributes to the development of children's social competencies like communication, cooperation, and empathy. Through play, children learn how to navigate conflicts while also honing their ability to take on social roles and relationships [22,26].

The developmental theory suggests that play helps children develop cognitive skills and abilities. In contrast, the social learning theory highlights how play offers opportunities for children to learn and practice social skills.

According to Sigmund Freud's theory of play, play acts as a window into a child's mind, allowing them to express and navigate their inner desires, conflicts, and fears symbolically. Freud believed children can fulfill their wishes through play and explore suppressed emotions [27].

Play allows children to act out scenarios, manipulate objects, and engage in role-playing that reflects their thoughts and feelings. For example, playing "house" might reveal insights into family dynamics and personal aspirations. Additionally, the symbolic nature of play enables children to address issues that they may not yet be able to express verbally or cognitively. Jean Piaget's theory on development highlights the importance of play in helping children grow cognitively and develop skills [28,29]. According to Piaget, children actively shape their understanding of the world by engaging in play activities that challenge their thinking. For instance, playing with blocks can teach children balance, spatial relations, and cause and effect. Piaget also identified stages of play such as play, constructive play, and pretend play, each contributing to enhancing cognitive abilities and problem-solving skills [28,29].

On the other hand, Albert Bandura's social learning theory suggests that play is a platform for children to learn skills through observation and imitation. Children can practice communication, negotiation, cooperation, empathy building, and understanding perspectives by engaging in role-playing scenarios during playtime [30,31].

2.2.3 Emotional benefits of Play

When children play together, they discover how their actions can impact others and adjust their behavior based on feedback. By playing, children pick up norms, values, and expectations that help them navigate complex social situations as they grow older.

The intricate relationship between emotions, mental well-being, and childhood play highlights a connection that shapes children's minds. Just like understanding feelings and nurturing health is important to building individuals, engaging in play is crucial for a child's overall development.

Awareness of emotions is vital to psychological growth, and participating in imaginative and unstructured play sets the stage for essential cognitive, social, and emotional skills. This thinking approach blends theory with practice by connecting psychology with education. Additionally, such a tool could symbolize the link between growth and play, effectively empowering educators, parents, and caregivers to support children who need it most.

2.3 Impact of Chronic Illnesses on Child Mental Health

Having examined self-regulation, mental well-being, and childhood play, it is also vital to acknowledge the impact that serious illnesses can have on a child's mental health and ability to manage emotions [32]. When children and teens face the challenges of illnesses or life-threatening diseases, the complex relationship between emotions, mental health, and play becomes even more crucial. Just as understanding emotions is vital to grasping the toll of these conditions, prioritizing health becomes essential in helping children build resilience over the course of treatment and recovery. Engaging in play promotes overall development and acts as a coping mechanism that allows children to work through their feelings and regain control of them amidst uncertainty [33].

2.3.1 Social Stigma

Another consideration is the impact of social stigma, which can worsen the difficulties faced by young patients. The labeling and discrimination against individuals with illnesses or other health conditions can lead to negative social, emotional, and psychological outcomes. Children dealing with stigmatized illnesses and conditions such as HIV/AIDS, mental health issues, chronic pain conditions, physical disabilities, and cancer are more vulnerable to mental health challenges [34].

Dealing with such conditions increases the likelihood of children facing discrimination and social exclusion. These experiences often lead to shame, guilt, and inadequacy, diminishing self-esteem and worth. Consequently, this can trigger anxiety, depression, and other mental health challenges [35].

To safeguard the mental well-being of children grappling with severe illnesses, it is crucial to offer tailored support and interventions. A robust support system may involve parents, educators, healthcare professionals, and social workers working together.

2.3.2 Common Mental Health Challenges

In the absence of support systems, children are susceptible to depression and anxiety – reactions to the stress associated with chronic illness diagnosis, treatment procedures, and recovery phases. Children often grapple with an array of emotions, such as fear, sadness, anger, and guilt, while simultaneously undergoing grueling illnesses' (such as cancer or chronic pain) treatments like chemotherapy, radiation therapy, potent medications, and surgical procedures [36].

Children facing illnesses may encounter challenges that hinder their lives, affecting their school participation, social interactions, and engagement in activities they love.

Additionally, they experience mental health issues that can manifest physically through symptoms like headaches, stomach aches, and fatigue.

Depression presents as a state of sadness, hopelessness, worthlessness, disinterest in enjoyable activities, changes in appetite or weight, sleep disturbances like insomnia, feelings of fatigue or lack of energy, difficulty concentrating or making decisions, heightened irritability, or anger outbursts. Conversely, anxiety is characterized by feelings of worry or unease that could lead to irregular breathing patterns, excessive sweating, an accelerated heart rate, and overall fatigue [37].

Examples of factors that can contribute to the development of depression and anxiety in children with chronic illnesses include [36]:

- The aggressiveness of the illness itself. The more aggressive the condition, the greater its psychological impact on the child.
- The seriousness of the illness (when a disease such as cancer is in its latest stages, it can lead to health issues and heightened emotional challenges)
- The impacts of treatment side effects
- Certain complications may develop, making a fragile patient more vulnerable.
- The child's age
- The child's understanding of their health condition and its implications increases the likelihood of increased levels of depression and anxiety.
- The child's physiological characteristics.
- Family medical history

Children who have illnesses such as neuroblastoma face a greater likelihood of experiencing significant emotional difficulties like post-traumatic stress, anxiety, and depression. To support these children in managing these issues, HealPet could integrate cognitive-behavioral therapy (CBT) strategies and biofeedback practices to help them manage anxiety and stress responses through exercises that alleviate anxiety while also teaching long-term stress management skills [38,39].

As diseases worsen over time, children with severe illnesses often go through anticipatory grief and depression. HealPet could potentially assist these children by employing storytelling and play techniques known as narrative therapy. These methods enable children to communicate their concerns and feelings effectively, helping them deal with emotions and feel empowered [40,41]. Moreover, this strategy facilitates the identification of deeper psychological issues, enabling caregivers to intervene promptly if needed. When children are undergoing treatments like chemotherapy, which can cause anticipatory anxiety and worsen physical symptoms, HealPet could provide virtual adventures and activities to distract and calm them. This approach would not only ease their anxiety but also enhance their treatment experience [42,43].

Children with long-term illnesses that involve challenges like sickle cell disease may experience heightened emotional sensitivity. The HealPet program could offer activities to build resilience in these children, such as guided visualization or relaxation strategies to help them cope with the uncertainties of their condition [44,45]. As children mature and gain an understanding of their condition, anxiety about the future may intensify. HealPet could address this issue by offering psychoeducational materials tailored to different age groups, empowering children with information that could ease their anxieties [46,47].

Children who have relatives with a history of mental health issues may be at a higher risk of developing similar conditions when dealing with long-term illnesses or stressors. A platform like HealPet could help with family-based interventions to create a nurturing atmosphere of emotional support and empathy. Having a strong family support system plays a crucial role in helping children cope with the emotional difficulties related to chronic illnesses [48,49].

Overall, parents, family members, and healthcare providers must be vigilant for signs of depression and anxiety at any stage (before diagnosis, during treatment, and post-treatment) [50]. Sensing technology, such as the child-centered device developed by this thesis, could help with such monitoring.

2.4 Treatment for Depression and Anxiety in Children with Illnesses

There are ways to help children dealing with illnesses manage their feelings of depression and anxiety. These methods include:

Therapy: Therapy can assist children in understanding and dealing with their emotions. There are types of therapy that have proven effective for children facing illnesses, such as cognitive behavioral therapy (CBT) and family therapy [51]. Among these options, family therapy stands out as an approach involving professionals working closely with the child's family. In the past, siblings and other family members were often kept separate from the patient.

The family's role in a child's life is crucial as family members play a part in caring for the child and making decisions. While those working with children and families usually rely on family members' insights into their children's needs, child life specialists also support each family member. Factors like stage coping mechanisms and specific situations are considered [52,53].

When it comes to treating depression and anxiety in children with illnesses, medication can be helpful. It should be used alongside psychotherapy for results. Support groups allow pediatric patients to share experiences and learn from others facing challenges.

Medical and therapeutic toys: Medical and therapeutic toys are tools that enhance well-being and development across age groups, mainly benefiting children and individuals with specific medical requirements. These creative interventions centered around play serve a function, offering fun and interaction while fostering mental and emotional development.

The following sections will delve into the foundational principles of these devices, examining their potential impact on enhancing emotional resilience and contributing to children's comprehensive cognitive, social, and emotional growth.

3. Play-Based Solutions

3.1 Play Therapy

Toys are essential for helping children cope with the stress and anxiety that often come with challenges like illnesses or hospital stays. For example, play kits that mimic fundamental medical tools help children understand procedures better and feel less scared about them, making them feel more in control over their health.

Therapeutic toys are also tailored to meet specific needs. For instance, therapists use sensory toys to help children with processing issues. These toys engage a child's senses using stimuli such as sound, scents, and textures. Toys focused on development provide opportunities for learning and problem-solving. Games like board games, puzzles, and building sets also enhance critical thinking, memory retention, and strategic planning skills. Children with disorders like autism spectrum disorder can benefit from these toys as they support growth in a fun and engaging way.

The toys mentioned above serve medical purposes and are typically utilized by medical professionals. They can also be applied holistically to support pediatric patients. By combining the features of these toys, a comprehensive approach can be taken to address the mental challenges associated with illnesses.

3.2 Toy Types

Recently, technological advancements have broadened the range of toys available in the medical field. Toys equipped with features and communication aids allow children with disabilities to engage more effectively with their surroundings, enhancing their playtime and overall growth. Moreover, these toys facilitate communication, empowering children to express themselves and build connections with others. Various types of toys are now accessible to aid in managing health issues for individuals in need. Some of these include:

Table 1: Toy Types

Toy Type	Description	Examples
Sensory Toys	Engage tactile senses and provide sensory stimulation. They are used for sensory integration therapy and benefit individuals with sensory challenges.	Sensory Balls, Tangle Therapy, Sensory Bubble Tubes
Fidget Toys	Small handheld devices designed to provide sensory input and help manage anxiety, stress, and attention-related issues.	Fidget Spinners, Fidget Cubes
Communication Aids	Apps and devices aid communication for non-verbal individuals through customizable communication boards and symbols.	Proloquo2Go, NOVA chat
Switch-Adapted Toys	Regular toys modified with adaptive technology to allow interaction for children with limited motor skills.	Switch-Adapted Plush Toys
Digital Play Kits	Combine physical play with digital games to promote learning in various subjects.	Osmo Genius Kit, LEGO Boost
l Reality Therapy	Immersive VR platforms are utilized for therapy, relaxation, pain management, and exposure therapy.	AppliedVR, Oculus Rift
tive Art Supplies	Art materials adapted for individuals with disabilities. Facilitate easier grip and use.	Special Supplies Adapted Art Kit
peutic Board Games	Games designed to promote social skills, emotional intelligence, and communication.	The Social and Emotional Competence Board Game
Companion Toys	Interactive toys that track routines, react to touch, measure activity, and offer companionship.	Smart Teddy Bear Companion, Interactive HUGS Plush Monkey

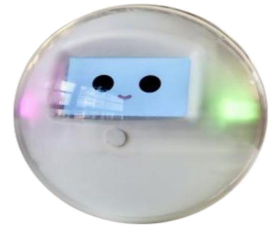
peutic Robots	Robotic companions designed to provide emotional support and interaction, particularly in healthcare settings.	PARO Therapeutic Robot, Robo Pets
hted Sensory Toys	Provide deep pressure and sensory input for calming and comfort, commonly used for sensory processing disorders, anxiety, or ADHD.	Weighted Stuffed Animals, Lap Pads

3.3 State of the Art

Aside from toys sometimes used for medical or educational purposes, specific models similar to HealPet already exist in the market. These toys offer various features such as tracking routines, reacting to touch, measuring physical activity, providing emotional support/companionship, and delivering therapeutic benefits. Here is a more thorough table showcasing products similar to HealPet, including features and limitations.

Table 2: State of the Art

Toy	Price	Key Features	Key Differences	Figure
Joy for all Companion Pet Cat	$125	-Responds to touch and sound with lifelike movements and purring	-No emotional monitoring tools, simple response to touch and sound -Not customizable for medical needs -Primarily for elderly, with some use in pediatric care for companionship	
PARO Therapeutic Robot	$ 6,000	-Responds to basic emotional cues (touch, sound) -Responds to touch and sound with lifelike movements and sounds -Used in medical settings	-Lacks detailed emotional monitoring -No health monitoring, general emotional comfort Primary used for elderly, and individuals with dementia	

Leka	$ 750	-Behavioral monitoring based on interaction patterns -Multi-sensory interactions (lights, sounds, vibrations)	-Focused on developmental disorders and cognitive support -General emotional monitoring	
Moxie by Embodied	$ 800 subscription	-Facial recognition, voice analysis, and interaction patterns to detect emotions -AI-driven interactions, emotional support through conversation, mindfulness exercises	-Not specifically for medical care -Focuses on general emotional and cognitive development -Data privacy concerns with facial recognition monitoring	

As these technologies are relatively new, there is still much to be done in this field concerning monitoring for serious illnesses such as illnesses. While toys and child life therapists can help children affected by these conditions, there is a lack of long-term monitoring to track their progress outside of hospital visits. The only one of these toys recommended in health settings is Paro and it is primarily used by elderly populations with dementia. Besides, while existing technologies focus on providing comfort through companionship, they do not include a combination of health monitoring and soft, tangible companionship (it seems like it is one or the other), they are costly (not accessible to many demographics) and are not tailored to our target group.

Essentially, we must move beyond creating a device that addresses self-regulation and incorporate mental health aspects. We must also meet the needs of children dealing with illnesses by offering customized support, building emotional resilience, and encouraging overall development. The aim is to achieve this while gaining an understanding of how awareness and play-based learning intersect to promote holistic well-being.

4. Design Goals and Approach

4.1 Objective

Informed by the reviewed background literature and related work, this section next discusses the design goals and constraints of our toy, which aims to promote play, build emotional resilience, and track longitudinal mental health in children in order to reduce disparities in treatment for pediatric patients. Specifically, our device (“HealPet”) is a physical object that monitors and soothes while attempting to encourage child play and socialization. The motivation behind constructing a physical toy rather than an app or other purely digital solutions is to encourage more engagement from the children and appeal to them through somatic interactions with. a physical companion that can enhance attachment and socialization. Research shows the significance of touch and hugs for socialization as a means to express and feel empathy and feelings of self-care, even in adults, as it stimulates the release of neurotransmitters such as dopamine and serotonin [54].

The following sections will delve into this device's foundational principles, examining its potential impact on enhancing emotional resilience and contributing to children's comprehensive cognitive, social, and emotional growth.

4.2 Criteria and Constraints

To create an optimal solution that aligns with our vision, we must first identify the criteria and constraints that guide and bind our efforts. Some of the design objectives of this project include:

Table 3: Criteria and Constraints

Criteria/Objective	CTQ (Critical to Quality)	CTI (Critical to Innovation)	Metrics/Benchmarks
Customization for individual children	Solution must be customized to each child's strength, physiognomy, expression of emotions, activity patterns, and genetics which affect their toy engagement and biometric data parameters. It requires understanding how each child expresses emotions differently and how their biometric data may vary based on genetics and normal activity levels.	Innovate adaptive algorithms that personalize toy engagement using AI or machine learning to account for each child's unique physical and behavioral patterns.	-Availability of personalized settings/options -ML models adaptation onto track emotions, behavioral patterns and physiognomy
Customization for the specific disease or health condition	Solution must be tailored to address the unique needs of children with specific diseases, considering factors such as disease type, treatment protocols, and psychological effects. This ensures that the toy effectively supports the mental health of children with diverse medical conditions.	Develop adaptive algorithms that can adjust the toy's functionality based on the child's current health status or treatment phase.	-Disease-specific customization options -Preliminary feedback from clinicians on disease-specific utility -Responsiveness to treatment phases
Acceptability	Must be accepted by clinicians, parents, and children alike. This involves ensuring that the technology is user-friendly, engaging, and aligns with the values and preferences of all stakeholders. Additionally, it must be comfortable and enjoyable for children, non-intrusive, and respectful of their privacy.	Create a user interface that is intuitive and universally accessible, while also providing educational tools to parents and clinicians on optimal usage.	-User satisfaction scores (children, parents, clinicians) -Time taken to learn/use interface (less than 5 minutes) -Privacy compliance based on initial design

Low Tech/Affordability	Solution must be affordable to ensure accessibility for children from different socioeconomic backgrounds. It should not exacerbate disparities in access to healthcare resources but rather foster community relationships and benefit children from any demographic equally. The technology and design should appeal to a broad range of users without favoring any particular social group.	Explore cost-effective materials and manufacturing processes that do not compromise on the quality or effectiveness of the toy's monitoring and soothing capabilities.	-Estimated production cost per unit (less than $55) -Expected retail price vs. average income brackets -Preliminary material quality assessments
Grounded in Scientific approach	Solution must be based on a scientific approach. It should provide clinicians with valuable information, complementing traditional monitoring and treatment methods. The data collected should be comparable over time to monitor improvement and inform clinical decisions effectively.	Introduce innovative data analysis methods that can provide predictive insights or early warning signs of distress or emotional upheaval.	-Correlation with expected clinical monitoring data (based on healthy child data) -Initial clinician feedback on potential utility -Short-term data retention and accuracy -Initial feedback from parents and clinicians on monitoring capabilities.
Safety and Comfort	Hypoallergenic materials must be used, and the sensors and electronics should be safely integrated to avoid any discomfort or harm to the child.	Research and implement new materials and sensor technologies that enhance comfort and safety, possibly using soft robotics or flexible electronics.	-Preliminary safety and comfort feedback from users -Observation of material response during short-term usage
Emotional Engagement and Soothing	Must effectively soothe the child and engage them emotionally, fostering a sense of companionship.	Innovate in the use of sensory feedback (vibration, sound, light) to create a dynamic and responsive toy that feels like a "living" companion for the child.	-Emotional engagement scores from initial user tests -Preliminary effectiveness of sensory feedback (measured through short-term child response) -Initial user engagement

These design objectives and constraints guide the project's development, ensuring that the smart toy effectively supports children's mental health needs while addressing practical considerations.

4.3 Prioritizing Potential Solutions

Based on the research and initial knowledge of the subject matter, I decided to make a first table of possible potential solutions. The potential solutions were then narrowed down after rating them based on the criteria outlined in the columns of the following matrix. Then, more edits were made after speaking with therapists and determining costs and feasibility following the iterations common in a human-centered design process.

1-5 scale for weights. One is the best; five is the worst.

Table 4: Priority Matrix

	Test complexity	Cost	Size	Invasiveness	Low tech	Precision	Physical toy	Total
Proprioceptive	1	1	2	1	1	5	1	12
Non-invasive biosensor	2	4	2	1	3	3	1	16
Invasive biosensors	2	5	3	5	3	1	3	22
App	2	1	1	1	5	4	5	19
Camera	1	3	2	5	2	2	4	19

Given the alternatives matrix above, we have determined that proprioceptive (motion and pressure) sensors combined with non-invasive biosensors (heart rate, oximetry) are worth exploring and using to create prototypes.

4.4 Envisioned Solutions

Derived from the previous matrix, we determined that our leading envisioned solution will use a combination of biosensors and physical sensors. These sensors will be processed using machine learning and then synthesized for the clinicians. The main biosensors incorporated into the intelligent toys will be oximetry and heart rate sensors. These sensors have been chosen since they are reliable (accurate and consistent readings) in various scientific studies. The primary physical sensors will be pressure and motion sensors.

Overview of Sensing Rationales and Responses for Pediatric Well-being Indicators

Table 5: Sensor Rationale

Indicator	Detection Approach	Sensing Rationale	Adaptive Response	Response Rationale	Priority Level
Anxiety-Panic Attack	Heart rate, oxygen levels	Elevated heart rate and changes in oxygen levels can be indicators of anxiety in individuals [55] RQ: How closely do fluctuations in heart rate and oxygen saturation levels in pediatric populations correlate with clinically recognized episodes of anxiety?	Emotional coping exercise, calming sound, alert caregiver/parent in case of extremities	RQ: Given the complexity of anxiety, how effective are various therapies, such as emotional coping techniques and auditory calming cues, for pediatric populations? What is the threshold for alerting caregivers?	High
Crying	Privacy-sensitive audio detection	Audio detection of crying can indicate various distress levels or needs [56]. RQ: How does audio detection of crying in pediatric emotional expressions distinguish between various degrees of distress, and what are the potential confounding variables in such measurements?	Distraction, alert caregiver/parent, log for review.	RQ: Using the principles of developmental psychology, what effects may different diversion techniques have on a child's emotional course during a crying episode, and under what circumstances becomes caregiver intervention critical?	High

Mood, Pain	Pressure sensors (e.g., in the toy's hands) EDA	When a child is in pain, angry, stressed, or sad they might grip or squeeze tightly. Alternatively, the EDA can be measured to assess Stress level, skin conductance, sweat gland activation, etc [57]. Given the subjective character of pain, how do pressure sensing via grip strength and EDA patterns compare or contrast in their capacity to predict children's pain experiences?	Alert caregiver/parent /physician, emotional coping exercise	RQ: How immediate and intense should the toy respond to detected pain indicators to ensure the child's safety and comfort? RQ: In terms of the therapeutic results for pediatric pain management, how do quick technology treatments compare and contrast with caregiver interventions?	High
Stress	EDA (Electrodermal Activity) sensors	As mentioned above, EDA measures skin conductivity, which can vary with stress levels and heart/respiratory rate [58]. RQ: How do EDA patterns in children appear during stress episodes, and how do these patterns shift across various pediatric age groups, taking developmental changes in stress physiology into account?	Distraction, emotional coping exercise, alert caregiver/parent	RQ: Which immediate interventions are most effective for children experiencing stress? When is it crucial to involve a caregiver? RQ: How could different immediate interventions affect the stress response trajectory in children, integrating findings from pediatric neurology and psychology?	Medium
Frustration, Anxiety	Accelerometer-based movement tracking, EMG, Gait Analysis	Prolonged inactivity can be tracked using a wearable that allows accelerometer-based gross movement tracking or EMG-based muscle activation tracking, or gait analysis using image processing can be used [59].	Gentle audio reminder to rest; log to review	RQ: How effective are audio reminders in promoting restful behavior in children? What patterns of inactivity should be of concern for caregivers? RQ: How might these patterns affect overall pediatric health and well-being?	Medium

The project's goal is to track the well-being of children by creating a toy-like device that can monitor their mental health. These interactive companions will have sensors to track pressure, movement, oxygen levels, and heart rate. By using these sensors, the toy can detect when a child is feeling upset and offer some soothing promptly.

Additionally, the project will focus on designing and making interfaces for the sensors in the stuffed toy. The design will prioritize comfort, safety, and appeal to ensure children enjoy playing with them. Incorporating these sensors will involve planning for managing power usage, processing signals, and communicating with devices for data collection.

5. Needfinding Approach

5.1 Human-Centered Design

The planned design takes into account standards and scientific principles and is enhanced through a design process focused on humans. We incorporated input from user interviews. Volunteering opportunities to make sure that the toy not only achieves its technical goals but also connects emotionally with children and families as well as healthcare providers. These fundamental understandings gathered from working with experts and engaging with children in healthcare environments have influenced the toys design significantly. Transforming it into a genuinely compassionate and efficient tool, for aiding in children's mental well being.

5.1.1 Interviews

To create an effective monitoring companion for children, we initiated a comprehensive needfinding approach that combined user interviews, sensor implementation, and prototype development. Partnering with Dartmouth Hitchcock Medical Center, we conducted interviews with children, healthcare professionals—including a pediatric oncologist, a team of five child life specialists, an end-of-life psychologist from DHMC, and a pediatric psychologist from Universidad Nacional Autónoma de Honduras (UNAH)—to gain a deep understanding of the emotional needs of children and their communication with parents and therapists. These interviews revealed common themes and direct suggestions that informed the design of the companion, ensuring it would be both functional and emotionally supportive. The interview questions are listed in Appendix IV.

Upon completion of interviews, valuable common themes were extracted through qualitative coding from the recordings and transcriptions. These themes as well as direct suggestions and their design implications are listed in the table below:

Table 6: Interview Feedback

Common Themes	Design Implication
Children dealing with illnesses commonly face emotions like fear, anxiety, depression, and loneliness. The intensity of these feelings can vary based on the child's age.	Tailor emotional support approaches according to the child's age. Younger children may benefit from small routines and techniques, while older ones might require more sophisticated tools for emotional processing.
Emotional reactions to diagnosis can encompass shock, denial, anger, and grief. Stressors related to treatment include concerns about pain, side effects, and disruptions to activities.	Offer age appropriate information about their illness and treatment to alleviate fears.
Effective techniques involve play therapy, art therapy and behavioral strategies. However, there are gaps in providing real time support.	Simplify controls and instructions for accessibility.
Toys should support therapists and their assessment methods and be easy for families to include in their everyday routines.	Provide guidance to families and caregivers on how to utilize the toy. Ensure that the toy's functionalities align with objectives and schedules.
Consistent feedback from users is essential for enhancement.	Create user feedback tools for children, families and healthcare providers. Regularly enhance the toy's features based on this feedback.
Evaluating long-term impact involves tracking mental well-being over time.	Implement long-term studies to evaluate the toy's efficacy. Focus on outcomes such as reduced anxiety, improved mood, and enhanced coping abilities.
Safety is crucial for children with weakened systems or severe pain.	Utilize non-hazardous, hypoallergenic materials and make the design easy to clean.
Personalizing the user experience boosts involvement and emotional engagement.	Let children customize how the toy looks and works based on their likes without reducing its monitoring efficacy. Provide options that can be adjusted to meet each child's mental requirements. Ask children to name the toy.

Based on the insights gained, we integrated movement tracking sensors, oximetry, and heart rate monitors into the plush toys, creating a working prototype that securely embeds these sensors. The data gathered from these sensors will be closely analyzed to identify patterns indicating when a child may be upset or experiencing mood changes. Feedback will be collected through surveys administered to patients, their families, and healthcare providers to assess the effectiveness and acceptance of these companions. This information will guide future iterations, which may include additional features such as voice recognition to enhance interaction and create a secure environment for the children.

The HealPet prototypes effectively met design requirements for helping children with illnesses by customizing emotional assistance. Moreover, the prototypes come with easy-to-use controls and clear guidance that make the toy accessible to both children and their families, supporting the goal of creating a user interface that is easy to understand. The prototypes are also designed to blend seamlessly into daily activities, supporting the evaluation techniques of therapists and making the toy a useful instrument in both medical facilities and households.

However, there are still areas that need more work, which will be addressed in the next steps and future plans. For instance, there is a plan to improve the toy's ability to provide real-time support by adding more advanced monitoring and response features (Future Work section). Additionally, mechanisms will be set up to collect feedback from children, families, and doctors to continually enhance the toy's features (Future Work section). Studies are planned to evaluate how the toy impacts mental health, such as reducing stress, improving mood, and helping children cope with their conditions (Longitudinal Studies and Contributions Section). Future versions of HealPet will prioritize the use of safe, hypoallergenic, and non-toxic materials to protect children with weaker immune systems (Appendices VI, VII). Furthermore, while the prototypes currently offer some level of personalization, upcoming updates will focus on giving children more freedom to customize both the appearance and behavior of their toy, thereby enhancing emotional connection without compromising the toy's monitoring capabilities (Future Work section). These efforts aim to enhance HealPet's functionality in meeting design expectations and making it an even more valuable tool in supporting children dealing with chronic illnesses.

5.1.2 Observation

To identify and better learn about the needs of the target users, we volunteered at the Dartmouth Hitchcock Medical Center under their palliative care wing as well as the Children's Health at Dartmouth (ChaD) Inpatient Unit. There, we interacted with many children aged 0-17, and parents going through illnesses. This provided an opportunity for our team to empathize with their daily lives. During our time there, we exclusively interacted with subjects in a volunteering capacity and not as researchers. We also ensured that cou activities complied with the HIPAA guidelines. Despite not being able to discuss our project nor anything pertaining or related to the sickness or the reason why the children were in this specific wing of the hospital, the time spent at the hospital provided insight into the interests and needs of children depending on their age. This experience allowed us to narrow down the target audience and get a rough sense of which toys were the child's favorites and why. It was an initial guideline for the first sketches and graphic designs.

Our time spent volunteering at Dartmouth Hitchcock Medical Center and Children's Health at Dartmouth (ChaD) Inpatient Unit gave us an understanding of what children truly value and require for their well-being and comfort. We noticed that younger children showed an interest in gentle and soothing toys that they could comfortably cuddle and play with–such as plush animals–which offered them a feeling of safety and friendship during challenging medical procedures. Older children seemed to lean towards toys that were interactive. Ones that could be customized or had “cool tech stuff” like built-in lights or sounds. These findings really emphasized the significance of making a toy that could cater to age groups by providing both a sense of comfort and engaging features that suit the child's developmental level. This insight played a role in shaping our design choices and led us to create prototypes that combine soothing physical shapes with interactive elements that can be adjusted based on individual preferences.

Our findings also showcased the importance of including fantastical,engaging animal figures in the toy creations. We observed that children showed a fondness for toys featuring animals like penguins, dragons and unicorns. These creatures not caught their eye with their attractive appearance but also sparked feelings of joy and intrigue making them perfect choices as sources of comfort, during challenging moments. The appearance and charm of these animal characters were factors, in attracting children to the toys; with vibrant colors and soft textures paired with playful expressions making the toys more appealing and interesting for them to interact with.The findings highlighted how crucial it is to incorporate both the attractiveness and emotional connection of these animal characters into the HealPet prototypes to create toys that are both comforting and captivating for children of various ages.

5.2 Incorporating HCD and Takeaways

The human-centered design process was informed by the interviews and the feedback gathered during the initial prototype testing. Common emotional challenges for children dealing with illnesses, such as fear, anxiety, depression, and loneliness, were identified and addressed in the design of the toy. Tailoring emotional support to a child's age was emphasized, with the toy offering different routines and techniques for younger children and more sophisticated tools for older ones.

The interviews also highlighted the importance of play therapy, art therapy, and behavioral strategies, though gaps in providing real-time support were noted. The toy's design was simplified to ensure accessibility and ease of use, aligning with the feedback that toys should support therapists and be easy for families to incorporate into their daily routines. Long-term studies will be implemented to evaluate the toy's efficacy, focusing on outcomes such as reduced anxiety, improved mood, and enhanced coping abilities.

Safety was a key consideration, especially for children with weakened immune systems or severe pain. The toys were designed using non-hazardous, hypoallergenic materials and were made easy to clean. Additionally, personalization options were introduced, allowing children to customize the toy's appearance and functionality to boost emotional engagement without compromising its monitoring capabilities.

6. Technical Features and Components

6.1 Technical Design

The above image shows an overview of the HealPet schematics. At the center of the HealPet lies an Arduino Nano board, which will connect to the sensor array. Once abnormal levels of anxiety or distress are detected, an alert circuit will trigger the emotional soothing port, displaying music or engaging the child with stimulatory motor wheels or LED lights. All the gathered data will be simultaneously fed to the ESP32, which we will receive via Bluetooth on our phones or other mobile devices. We will delve deeper into each of the components and functionalities in the following sections.

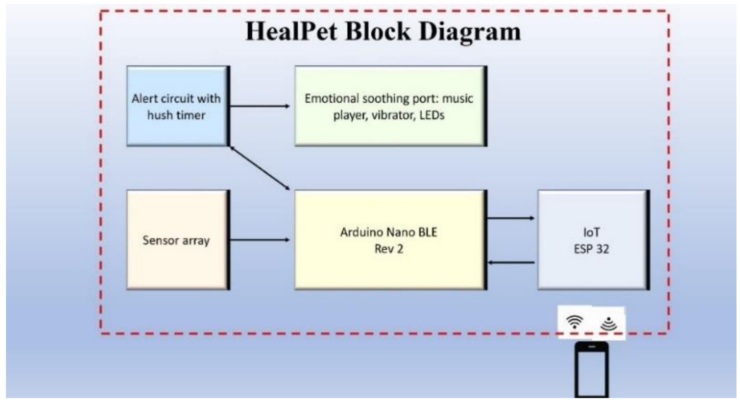


Figure 1: Block Diagram overviewing electronic components

6.1.1 Boards

Arduino is an open-source, compatible platform for electronic beginners. Many online tutorials show how to connect the boards, sensors, and LED lights and set up the circuits. The easy-to-use software and hardware interfaces allow people of all ages and skills to create projects of their imagination [60].

The Arduino Nano 33 BLE Sense Rev 2 is a versatile board that utilizes the nRF52840 microcontroller with Bluetooth Low Energy (BLE) capabilities. This board is ideal for sensor-based projects due to its compact size, flexibility, and compatibility [61].

The ESP WROOM 32 ESP32 Development Board can be used as a foundation for making intelligent toys focused on monitoring health. With its dual-core microcontroller, wireless connectivity choices, Arduino adaptability, and integrated sensors, this device is perfect for incorporating features and developing interactive experiences geared toward enhancing mental wellness [62].

Table 7: Microcontroller Boards

Feature	Arduino Nano 33 BLE Sense Rev2	ESP-WROOM-32 ESP32 Development Board
icrocontroller	Nordic nRF52840 (ARM Cortex-M4 CPU @ 64 MHz) [61]	ESP32 (Dual-core Tensilica LX6 @ up to 240 MHz) [62]
Integrated Sensors	Accelerometer, Gyroscope, Magnetometer, Environmental Sensors, Microphone, Gesture sensor [64]	Various sensor interfaces such as GPIO pins (e.g., heart rate, temperature, accelerometers) can be integrated) [63]
Wireless Connectivity	Bluetooth Low Energy (BLE) [64]	Wi-Fi (2.4GHz), Bluetooth, BLE [63]
Form Factor	Compact	Standard development board form factor
USB Interface	USB for programming, debugging, and as a host [64]	Type-C USB interface [63]

Energy Efficiency	Designed for energy efficiency [64]	Designed for low power consumption [65]
Processing Power	Ample processing power for various applications [64]	Enhanced processing capabilities for real-time monitoring [63]
Arduino IDE Compatibility	Yes [66]	Yes [63]
Open-Source Community Support	Yes [60]	Yes [63]

The sensor interface offers a range of opportunities for projects involving tracking movement, monitoring behavior, and implementing AI applications. Currently, we plan to use sensors. Leveraging the Arduino Nano is beneficial due to its sensor compatibility. The ESP32 development board boasts a variety of peripherals like GPIO pins and sensor interfaces that can be harnessed to integrate sensors for mental health monitoring. These sensors might include heart rate monitors, temperature sensors, accelerometers, and biofeedback sensors, facilitating real-time data collection for analysis and feedback [63].

The nRF52840 microcontroller drives the Arduino Nano 33 BLE Sense Rev2. It is a 32-bit ARM Cortex M4 CPU running at 64 MHz to deliver sufficient processing power for various applications. The ESP32 chip houses two potent Tensilica LX6 microprocessor cores that enhance processing capabilities. This dual-core setup allows for multitasking and simultaneous task execution, making it ideal for monitoring real-time mental health metrics.

The wireless connectivity features of the Arduino Nano enable communication with BLE devices, like smartphones, tablets, and computers. The ESP32 module is well-suited for developing projects and applications that need connectivity. It supports both 2.4GHz Wi-Fi and Bluetooth, allowing communication with devices and networks. This capability enables toys to connect to the internet for data collection, syncing with cloud services and remote monitoring, enhancing their features and accessibility [60].

Regarding energy efficiency, the nRF52840 microcontroller in the Nano 33 BLE Sense Rev2 is tailored for optimized power consumption, making it ideal for battery-operated projects [61]. Despite its performance capabilities, the ESP32 microcontroller is designed to consume power, making it a good fit for battery-powered smart toys meant for continuous monitoring over long periods.

Regarding Arduino compatibility, the Nano 33 BLE Sense Rev2 can be used with the Arduino IDE like Arduino boards, ensuring a user development environment with libraries and a supportive community of makers and developers [66].

With robust open-source community support backing both the Arduino Nano and ESP32 platforms, users have access to a pool of resources, libraries, and tutorials. This active open-source community promotes collaboration and innovation among developers, allowing them to tap into existing tools and knowledge to craft toys focused on mental health monitoring.

When we pair the Arduino Nano 33 BLE Rev2 with the ESP WROOM 32 ESP32 Development Board, we can harness the features of both platforms to design smart toys that can instantly track different mental health signals [67,68]. This pair's small size, energy efficiency, connectivity, and sensor integration features make it a perfect option for enhancing wellness through engaging and linked devices.

6.2 Prototyping a child-centered sensing device

To create a prototype of a toy aimed at identifying distress and anxiety in children, tracking three aspects—psychological, physiological, and behavioral—can offer a comprehensive evaluation of the child's mental well-being. Children can examine these aspects to ensure the toy's effectiveness and user-friendliness.

6.2.1 Psychological Aspect: Crying Sound Analysis Using Voice Recognition

The interactive toy could be fitted with a microphone and voice recognition technology to analyze crying sounds. By identifying patterns in the child's cries, like their frequency, intensity, and duration, the toy can evaluate the child's state and recognize signs of distress or anxiety. This analysis can be conducted directly on the toy and transmitted to a linked app for assessment, ensuring prompt feedback and support if necessary.

6.2.2 Physiological Aspect: Monitoring Heart Rate and Oxygen Levels

The interactive toy features sensors for monitoring the child's heart rate and oxygen saturation levels (oximetry). Changes in these parameters can indicate heightened stress or anxiety levels, providing information for evaluating the child's mental health.

The toy can show these measurements to children in an easy-to-understand way, such as animations or simple graphics, to help them grasp how their bodies react to stress and anxiety.

6.2.3 Behavioral Measurement: Pressure, Steps and Movements/Jerky Motions

In an early version of HealPet it was necessary to prioritize simplicity and reliability in the initial design. Despite listing pressure sensors as high priority in Table 5, introducing pressure sensors at this stage might have added complexity to the prototype, potentially leading to calibration challenges and inconsistent data collection. I decided it was more important to start with one sensor for each of the three identified aspects of the emotional and overall well-being. Pressure sensors will be incorporated in future iterations once the primary functions are fully optimized and user feedback is incorporated. The initial development phase prioritized combining some monitoring information and soothing components before expanding the functionality. Pressure sensors will be the next addition for future iterations once the foundational elements are perfected and user feedback has been incorporated.

The initial smart toy includes an accelerometer to track a child's steps and movement and analyze patterns. Jerky motions have to be differentiated from general restlessness and fidgeting, which could be indicators of anxiety and, thus, overall behavior.

Through the integration of all three measures, we aim to create a comprehensive, non-invasive method for monitoring distress and anxiety, which will allow us to get an idea of the child's mental health status.

7. Hardware Implementation

7.1 Physiological-Biosensors

7.1.1 MAX 30102:

The MAX30102 module integrates a unit's pulse oximetry and heart rate monitoring features. It includes LEDs, photodetectors, optical elements, and low-noise electronics to reduce interference from surrounding sources. Developed by Maxim Integrated, the MAX30102 is an optical sensor module tailored for applications that require heart rate and blood oxygen saturation monitoring using photoplethysmography (PPG) techniques. Combining components and integrated circuitry in a compact package, the MAX30102 has become popular for wearable health devices, fitness trackers, and medical monitoring tools [69].

Key Features:

Table 8: MAX30102 Technical Features

Feature	Description
Integrated Photodetector	Incorporates a photodetector that captures the reflected light from the skin (essential for PPG signal acquisition) [70]
Signal Processing Circuitry	Signal processing circuitry is incorporated to extract the PPG waveform from captured signals and to compute heart rate and SpO2 values.
Real-Time Monitoring	Allows timely monitoring of physiological parameters (i.e., heart rate and SpO2). This timely feedback is excellent for healthcare applications.
Ambient Light Cancellation	Includes ambient light cancellation to improve the accuracy of PPG measurements by reducing interference from external light sources.
Low-Noise Signal Processing	Includes low-noise signal processing to enhance the signal-to-noise ratio (SNR). Overall, it improves the quality of the PPG signal.

Flexible I2C Interface	Communicates with external microcontrollers using the I2C interface for easy integration into various electronic devices.
Low Power Consumption	Designed for low power consumption. Suitable for battery-powered applications such as ours [69]
Compact Form Factor	Compact size and low-profile package, suitable for integration into wearable devices, fitness trackers, and other portable healthcare monitoring applications.

The MAX30102 sensor module has applications in fields such as:

- Medical Monitoring Devices, such as this toy, are used for continuous, semi-continuous, or sporadic monitoring of patients' vital signs, including heart rate and blood oxygen levels.
- Health and Fitness Monitoring: Monitoring heart rate and SpO2 levels during workouts may offer insights into users' fitness and performance.
- Sleep Tracking: Sleep patterns can be predicted and studied by tracking heart rate and oxygen level changes.
- Stress Detection: Use heart rate variability to gauge stress levels and assist individuals in managing stress.
- Remote Monitoring: allows healthcare providers to monitor patients' health parameters in time.

All of the above impact emotional well-being and can, thus, be considered for future versions of the toy.

7.1.2 Measuring Heart Rate and Blood Oxygen Level

The MAX30102 sensor contains two LEDs, one emitting red light while the other emits infrared light. In addition to the lights, a photodetector also captures light passing through the fingertip. Blood hemoglobin absorbs light at different amounts depending on oxygenation. More oxygenated blood absorbs higher amounts of infrared light and less red light; alternatively, less oxygenated blood absorbs more red light and less infrared light. The photodetector receives the light from both LEDs after it passes through the subject's finger and converts the intensity changes into signals [69].

The heart rate measurement relies on oxygenated hemoglobin in blood-absorbing infrared (IR) light. The oxygen in the blood (higher hemoglobin concentration) the IR light it absorbs. As the heart pushes blood through the finger with each beat, changes in reflected IR light lead to a fluctuating waveform at the photodetector's output. By shining light on the finger and collecting readings from the photodetector, we can obtain a pulse reading for heart rate (HR) [69].

The heartbeats are detected when the reflected light on the photodetector reaches a peak representing the maximum blood volume per cardiac cycle. The time interval between each peak is detected and then an equation is derived.

$$HR = \frac{60}{\Delta t} \text{ or}$$

$$HR = \frac{60}{\frac{1}{n}\sum_{i=1}^{n} \Delta t_i}$$

Essentially, this calculation comes from the time interval between peaks corresponding to the pulsatile blood volume changes in the tissue.

To calculate oxygen levels, the device first assesses the absorbance of light at two wavelengths at the peak and lowest points of the heartbeat cycle. It is based on the ratio of the absorbance of red light (at 660 nm) to infrared light (at 940 nm) by the blood.

Beer-Lambert Law

The Beer-Lambert law describes how light is absorbed as it passes through a substance. The basic form for a single wavelength is:

$$A_\lambda = log\left(\frac{I_0}{I_\lambda}\right) = \epsilon_\lambda \cdot C \cdot L$$

where;

- A_λ is the absorbance at wavelength λ.
- I_0 is the initial light intensity.
- I_0 is the transmitted light intensity after passing through the material.
- ϵ_λ is the molar absorptivity at wavelength λ.
- C is the concentration of the absorbing species.
- L is the path length through the material.

For two wavelengths (red and infrared), the absorbance at each wavelength can be expressed as:

$$A_{red} = \epsilon_{red,oxy} \cdot C_{HbO_2} \cdot L + \epsilon_{red,deoxy} \cdot C_{Hb} \cdot L$$

$$A_{IR} = \epsilon_{IR,oxy} \cdot C_{HbO_2} \cdot L + \epsilon_{IR,deoxy} \cdot C_{Hb} \cdot L$$

where;

- A_{red} and A_{IR} are absorbances
- $\epsilon_{red,oxy}$ and $\epsilon_{IR,oxy}$ are the molar absorptivities of oxyhemoglobin (HbO_2) at the red and infrared wavelengths.
- $\epsilon_{red,deoxy}$ and $\epsilon_{IR,deoxy}$ are the molar absorptivities of deoxyhemoglobin (Hb) at the red and infrared wavelengths.
- C_{HbO_2} and C_{Hb} are the concentrations of oxyhemoglobin and deoxyhemoglobin, respectively.

The light intensities at the red and infrared wavelengths after passing through the tissue can then be expressed rewriting the Beer-Lambert law as follows:

$$I_{red}(t) = I_{0,red} \times e^{-\alpha_{red} \cdot C(t) \cdot L}$$

$$I_{IR}(t) = I_{0,IR} \times e^{-\alpha_{IR} \cdot C(t) \cdot L}$$

where;

- I_{red} and I_{IR} are the light intensities at the red and infrared wavelengths, respectively.
- $I_{0,red}$ and $I_{0,IR}$ are the initial light intensities.
- α_{red} and α_{IR} are the absorption coefficients at these wavelengths.
- $C(t)$ is the time-varying concentration of blood, related to the pulsatile flow.

The total absorbance at each wavelength can be broken down into the DC (constant) and AC (pulsatile) components:

$$A_{red}(t) = A_{DC,red} + A_{AC,red}(t)$$

$$A_{IR}(t) = A_{DC,IR} + A_{AC,IR}(t)$$

where;

- $A_{DC,red}$ and $A_{DC,IR}$ are the DC components, corresponding to the baseline absorption due to non-pulsatile tissues and constant blood volume.
- $A_{AC,red}(t)$ and $A_{AC,IR}(t)$ are the AC components, corresponding to the pulsatile changes in blood volume with each heartbeat.

Based on the last two equations, the absorbance at a given time t can be expressed as:

$$A_{red}(t) = log\left(\frac{I_{0,red}}{I_{red}(t)}\right) = \alpha_{red} \cdot C(t) \cdot L$$

$$A_{IR}(t) = log\left(\frac{I_{0,IR}}{I_{IR}(t)}\right) = \alpha_{IR} \cdot C(t) \cdot L$$

Now we can solve for AC and DC. DC (non-pulsatile) components are derived as follows:

$$A_{DC,red} = \alpha_{red} \cdot C_{DC} \cdot L$$

$$A_{DC,IR} = \alpha_{IR} \cdot C_{DC} \cdot L$$

AC (pulsatile) components are derived as follows:

$$A_{AC,red}(t) = \alpha_{red} \cdot \Delta C(t) \cdot L$$

$$A_{AC,IR}(t) = \alpha_{IR} \cdot \Delta C(t) \cdot L$$

Where:

- $\Delta C(t)$ represents the time-varying component of the blood concentration, i.e., the part that changes with the heartbeat.

The primary calculation involves creating a ratio between the measurements of light and infrared light for both the contraction and relaxation phases of the heartbeat, which can be expressed as:

$$R = \frac{\left(\frac{AC_{red}}{DC_{red}}\right)}{\left(\frac{AC_{IR}}{AC_{IR}}\right)} = \frac{(AC_{red} \cdot AC_{IR})}{(AD \cdot DC_{IR})}$$

The AC and DC components are calculated through the Beer Lambert's Law which is fundamental to understanding how the ratio of absorbances (or intensities) at different wavelengths so it can also be expressed in terms of:

$$R \approx \frac{\epsilon_{IR,oxy} \cdot C_{HbO_2} + \epsilon_{IR,deoxy} \cdot C_{Hb}}{\epsilon_{IR,oxy} \cdot C_{HbO_2} + \epsilon_{IR,deoxy} \cdot C_{Hb}}$$

Empirical Equation: The determined ratio (R) is then plugged into an equation established through calibration with a medically approved pulse oximeter such as a blood gas analyzer, linking the ratio (R) to SpO2 levels.

$$Sp0_2 \approx A - B \times R$$

The values of A and B are established by applying linear regression or a similar curve fitting technique that minimizes the error between the calculated SpO2 values (from the formula) and the actual SpO2 values (from the reference method) where A corresponds to the intercept and B to the slope.

This method enables the device to predict blood oxygen saturation (SpO2) using photoplethysmography (PPG) technology (non-invasively).

A research study by IJEECS found that heart rate and oxygen saturation (SpO2) measurements achieved an accuracy rate of 97.11% and 98.84%, respectively, when utilizing the sensor [70].

The MAX30102 stands out as an optical sensor module that has carved out its place in health, fitness, and medical fields due to its monitoring capabilities for heart rate and SpO2 levels.

Due to its size, easy-to-use interface, and dependable performance, the MAX30102 has become a popular choice among developers and manufacturers seeking to add vital sign monitoring to their devices. Its ability to streamline the integration process for wearable devices makes it an excellent option for the stages of project development.

7.2 Behavioral-Proprioceptive Sensors

Proprioceptive sensors, which sense changes in body movement and position, can be incorporated into a toy to gather insights into a child's activities and motions [71]. Designing a toy with built-in sensors involves integrating accelerometers, gyroscopes, or pressure sensors into the toy's framework. These sensors can detect alterations in posture, gestures, and movements, offering an understanding of how a child engages with the toy and their surroundings. The information gathered can then be examined to establish connections between actions and potential signs of well-being.

Fostering Self-Regulation:

Children often express their state through actions. A toy equipped with sensors can help children develop self-regulation abilities. For example, the toy could offer feedback when it detects increased anxiety-related movement patterns. Children could learn to recognize these feedback signals and apply self-soothing techniques with time.

Early Identification and Support:

Specific mental health issues exhibit signs. Monitoring how a child interacts with the toy can detect subtle shifts in movement patterns. These variations could act as warnings of concerns, prompting caregivers to start discussions or seek professional assistance.

Monitoring Progress in Child Development:

The sensors in the toy play a role in keeping track of how children reach milestones. Any deviations from the motor development could signal delays or disorders in development. Collecting data can aid in spotting challenges early on, allowing for timely interventions to be set in place. Through the toy's sensors, caregivers can observe a child's state by picking up subtle movements linked to different emotions. For instance, an increase in fidgeting might indicate feelings of anxiety or restlessness. By monitoring these movements, parents and caregivers can understand how a child responds emotionally and how these responses change over time.

7.2.1 Accelerometer

The accelerometer measures acceleration commonly denoted as 1g or 9.81 m/s^2 in conditions. These devices can detect motion in three dimensions.

Piezoelectric accelerometers utilize pressure on materials to generate an electric charge. Tiny piezoelectric particles with mass sense acceleration, converting them into charge and then converted into velocity values.

On the other hand, capacitive accelerometers rely on changes in capacitance caused by plate displacement. Some systems have plates connected to springs that adjust capacitance with plate movement due to acceleration. The differential capacitive accelerometer uses capacitors for measurement, where fixed capacitors are attached to anchors, and a movable proof mass detects acceleration by altering capacitor electrode spacing and capacitance.

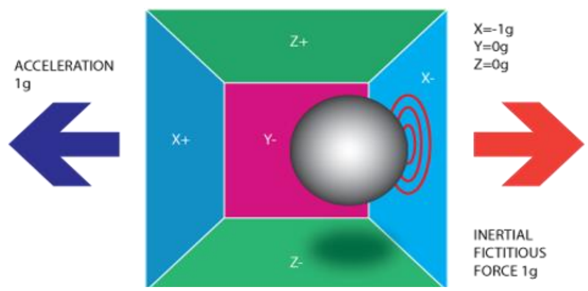


Figure 2: Accelerometer [72]

For this project, we will be utilizing the ADXL335, which detects changes in capacitance when subjected to acceleration..The ADXL335 gives analog voltage outputs that represent the acceleration, in the X, Y and Z directions. Each axis (X, Y, Z) has its output pin and the voltage on each pin changes based on the acceleration along that axis. The usual voltage range is from 0V to the power supply voltage (3V or 3.3V) with an output of 1.5V when the sensor is not moving (assuming no acceleration besides gravity).

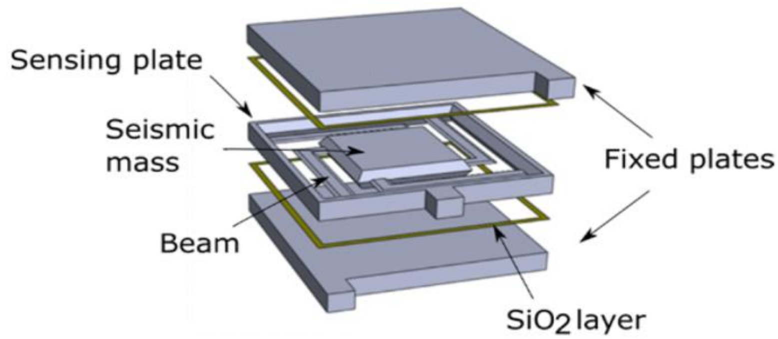


Figure 3: Capacitive

The ADXL335 has a sensitivity of around 300 mV/g (where "g" represents gravity's acceleration, 9.81 m/s^2).

This sensor can measure accelerations within ±3g limits indicating it can detect motions between 3g and +3g on each axis.

7.2.2 Calculate Acceleration

Measure the Output Voltage:

Read the output voltage from the ADXL335 sensor for the X, Y, and Z axes.

Subtract Zero-g Bias:

Subtract the zero-g bias voltage (typically 1.5 V) from the output voltage for each axis.

$$\Delta V = V_{out} - V_{zero-g}$$

where;

- V_{out} is the measured output voltage.
- V_{zero-g} is the zero-g bias voltage (e.g., 1.5 V).

Divide by Sensitivity:

Divide the result by the sensitivity (300 mV/g or 0.3 V/g) to get the acceleration in $g = 9.81 m/s^2$ (acceleration due to gravity).

$$Acceleration\ (in\ g) = \frac{\Delta V}{Sensitivity\ (in\ V/g)}$$

Acceleration (in g)= ΔV/Sensitivity (in V/g)

where;

- ΔV is the voltage change calculated in the first step.
- Sensitivity is the change in output voltage per unit of acceleration (e.g., 0.3 V/g).

7.2.3 Accelerometer in studies

The compact and precise ADXL335 accelerometer is well-known for its design. It is commonly used in devices to track children's steps and movements. According to a study by Tudor Locke et al., accelerometers are considered tools for measuring children's physical activity levels, capturing low-intensity activities like walking and higher-intensity movements [74]. Using accelerometers, including the ADXL335 model, allows for monitoring children's activity patterns throughout the day, as highlighted in research by Brønd et al. [75].

Additionally, studies show a link between activity levels and behavioral changes in children. For example, research by Lopes et al. revealed that increased physical activity is connected to enhanced function, reduced hyperactivity, and improved mood regulation among children [76].

Using devices like the ADXL335 accelerometers to monitor how active children are, caregivers and healthcare providers can monitor any behavior changes over time, as discussed in studies such as those by [77,78].

Moreover, wearable devices with the ADXL335 accelerometer offer real-time tracking features, allowing action when unusual activity patterns are detected. This ability is especially beneficial for recognizing shifts in behavior or underlying health conditions in children, as shown in studies by [79,80].

The ADXL335 accelerometer is a tool for tracking children' steps and acceleration. It offers insights into their physical activity levels that can be linked to changes in behavior. By combining this technology with research, caregivers and healthcare professionals can encourage habits and better monitor children's well-being.

7.3 Piezoresistive Sensors to Assess Psychological State

7.3.1 Audio Detection

An audio sensor works by picking up waves from the surroundings through a microphone. The microphone changes these waves into electrical signals. This process involves kinds of microphones like electret condenser microphones (ECM) dynamic microphones or MEMS (Micro Electro Mechanical System) microphones [81,82,83].

Once the sound is captured and turned into a signal it needs to be amplified. Amplification is done by an amplifier circuit that enhances the signal's strength [84]. In instances the amplified signal goes through filtering to get rid of noise or specific frequency ranges that aren't needed for the task at hand. For example a low pass filter might be employed to eliminate high frequency noise or a band pass filter could isolate a frequency range to the system [85].

Following amplification and filtering processes in systems where applicable the analog electrical signal must be converted into digital form. This transformation is carried out through an Analog to Digital Converter (ADC) which samples the analog signal at intervals and converts it into digital signals [84]. The accuracy and effectiveness of detection heavily rely on the sampling rate, which indicates how many samples are captured per second. Higher sampling rates offer sound information but also demand increased processing power and storage [86].

After digitization software can analyze the signal to identify sounds or patterns. This analysis may involve recognizing speech detecting presence or pinpointing audio occurrences like claps, alarms or other significant noises [87]. Sophisticated systems may delve deeper by examining frequency, amplitude and duration to extract characteristics such as pitch, volume or rhythm for further processing or decision-making purposes [86].

The final step in operating a detection sensor entails triggering a response based on analysis of sounds. For instance, when a loud noise is detected by the system it could activate an alarm, send out a notification or start recording [87]. In certain systems a sensor can fine tune its sensitivity or filter settings through a feedback loop adapting to its surroundings to enhance accuracy and performance gradually [85].

7.3.2 The Voice Recognition Module V3

The Voice Recognition Module V3 is an Arduino-compatible device that supports voice recognition and shows potential for monitoring symptoms in children. It identifies crying patterns and analyzes factors like pitch, intensity, and duration to differentiate between distress, hunger, and pain cries. Studies suggest that these crying patterns can indicate states and needs in infants and young children [88].

Combining the Voice Recognition Module V3 with machine learning algorithms can create a customized cry analysis system for each child. Training the system on a dataset of labeled crying patterns associated with states such as anxiety, sadness, or discomfort enables categorizing different types of cries. This method has been proven effective in studies examining automated cry analysis systems to identify signs of postpartum depression in mothers [89].

In real-world scenarios, caregivers or healthcare providers could use the Voice Recognition Module V3 within a monitoring setup integrated into a child's surroundings, such as a crib or nursery.

The system can instantly analyze the sound features when it picks up on crying sounds. Send alerts or messages to caregivers through a connected device, like a smartphone app or computer interface. This prompt feedback enables assistance. Care for children going through emotional distress, aiding in the early detection and handling of mental health issues. Unfortunately, our project's code could not identify crying patterns due to a lack of data to train a machine-learning model. Moreover, the Arduino Nano lacks enough SRAM capacity to process such large amounts of data. Moving forward, we plan to incorporate voice recognition as a sensor. Working code can be found in Appendix III.

8. Soothing

Another critical component of the toy was to improve a child's mental state by providing comfort and company. This criterion was attempted by making the toy a desired companion that the child could take care of and seek comfort during their anxious moments. A safe mental space was created using projected care. We define projected care as projecting certain feelings and actions of self-keeping onto another thing/person, in this case, an animal persona. Through this outward attribution of positive feelings, the child will learn to empathize and socialize with others and later internalize these emotions into the self.

8.1 Outward Design

We created several toy designs to appeal to the children and then asked them to evaluate and choose their favorites. We initially created models on Blender, which were later 3D printed with thermoplastics. These models will be developed into stuffed animals used as archetypes for the final refined products that will hold the sensory design.

8.1.1 3D printing process

The iterative 3D printing process for toy production involved experimenting with different materials, support strategies, and design optimizations to overcome challenges and achieve the desired quality and functionality. Initially, TPU (thermoplastic polyurethane) was chosen for its flexibility and durability; however, difficulties arose in support removal without damaging the design due to solid bonding, as shown when printing the first two unicorn models, a small one at the machine shop and a normal sized-one at Maker's Space. This realization aligns with the findings by Tymrak et al., who highlighted the challenges of printing with flexible materials like TPU, particularly in achieving optimal mechanical properties and surface finish under realistic environmental conditions [90].

Subsequently, PLA (polylactic acid) was tested as an alternative, offering easier support removal but lacking the desired softness for comfortable play, which is consistent with the known rigidity of PLA compared to TPU [91]. A multiprinter approach was adopted, utilizing PLA for the supports and TPU for the toy to address the previous issue. However, challenges persisted, especially with these larger toys, as TPU prints struggled to maintain quality, corroborating studies by Ahn et al., 2009 on the anisotropic material properties of fused deposition modeling (FDM) prints [92].

Further refinements were made by adjusting printing parameters, such as overhang threshold from 40 to 50 and infill density from 0 to 5 percent. Parameters were also changed from 4 to 3 to enhance texture and comfort, in line with the importance of parameter optimization highlighted by Bhushan et al. [93]. Additionally, design modifications, including optimizing support placement and internal space allocation, were identified as crucial steps for successful printing, echoing the findings of Zhang et al., 2019 on strategies for printing hierarchical structures inspired by biological materials [94]. Despite these efforts, challenges persisted with specific designs, such as unicorns and dragons.

The PLA models and the best TPU with PLA support models were painted to mimic the appearance of the Blender models and the future stuffed animals. Due to the hardness of the PLA models, it was decided that they were unsafe for play and the TPU models did not meet the expected quality. Therefore, testing was conducted using stuffed animals that were bought from other stores online.

8.2 JITAI Adaptive Features

Just-in-time adaptive interventions (JITAIs) are a type of adaptive intervention that can be delivered at any particular moment of time at precisely the time and place that it is needed. It is designed to offer the right amount of help given the internal and contextual state surrounding the user.

Through a synergy of sensor technology, machine learning, and compassionate design, HealPet becomes a sensitive companion capable of recognizing subtle changes in a child's emotional state. By analyzing physiological cues such as heart rate, oxygen levels, vocal tone, and other physical interactions with the toy, the toy can proactively detect signs of anxiety, distress, or discomfort and offer an approach to provide comprehensive support.

Firstly, the system deploys soothing distractions such as gentle music, comforting messages, calming vibrations, and soothing lights. These mechanisms are carefully designed to divert the child's attention and provide immediate comfort during distressing times. This proactive intervention creates a therapeutic ambiance, helping to alleviate negative emotions.

The final prototype will contain music that will play upon detecting anxiety levels or crying in the child and upon the child's command. Furthermore, we included vibration actuators, light sensors, and music. Later models will also include a touch and light sensor, and will arrange these features found as they are found in commercial toys, similar to the diagrams below:

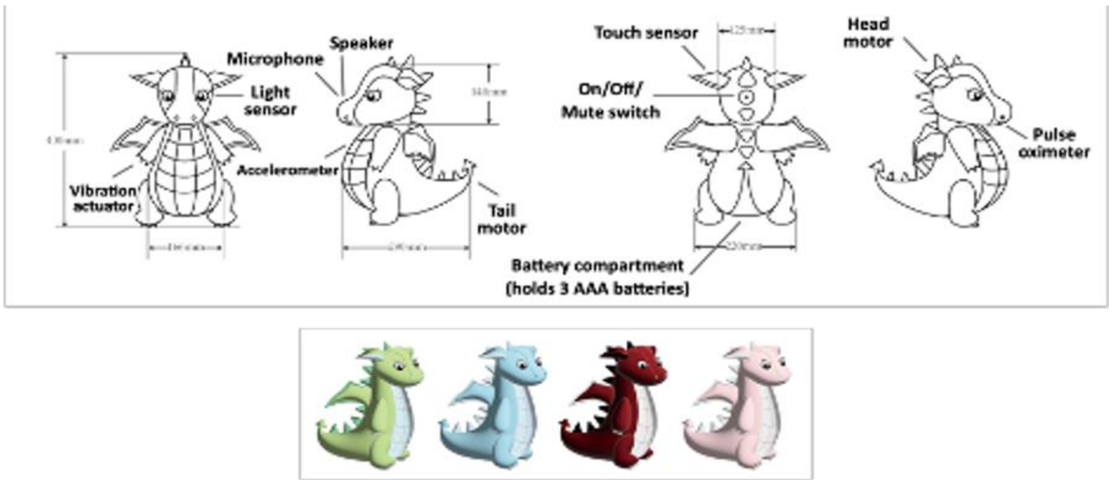


Figure 4: Diagram of sensor components in a dragon-like plushie form factor

Similar to weighted sensory toys, HealPet was designed to provide sensory input through pressure and proprioceptive stimulation. These toys often incorporate various materials and electrical components to enhance their soothing effects.

Vibration Motor: At the core of the HealPet is a vibration motor. This motor generates gentle vibrations, which create a non-painful sensory input that competes with the pain signals transmitted through the nervous system. The brain's limited attention capacity can be directed towards the vibrations, effectively reducing the perception of pain and distress [95].

Deep Pressure Stimulation: Deep pressure stimulation is the primary soothing mechanism of weighted sensory toys. The added weight applies gentle, even pressure to the body, which can help regulate the sensory system and induce a calming effect. This sensation is akin to a comforting hug and can promote relaxation [96,97].

LED Lights: HealPet prototypes incorporate LED lights that can be visually engaging for patients. These lights can help draw attention away from the medical procedure and onto the colorful, soothing visual stimuli provided by the device [98,99].

Music: Famous children's music tracks were included and reproduced by command or triggered by high anxiety levels [100,101].

Power Supply: HealPet is powered by replaceable or rechargeable batteries, ensuring portability and ease of use. The power supply is an essential component that ensures consistent operation of the vibration motor and LED lights.

Psychological Comfort: HealPet's friendly and approachable design contributes to its soothing mechanism. The presence of a visually appealing and non-threatening device can alleviate anxiety and fear associated with medical procedures, promoting a sense of control and comfort.

Cognitive Focus: The engagement provided by the toy, whether through music, vibrations, or LED lights, can divert cognitive focus from stressful situations or overwhelming sensory environments. This redirection of attention can be particularly beneficial for individuals who experience sensory overload. This distraction mechanism capitalizes on the brain's capacity to process multiple stimuli, reducing the brain's ability to perceive an anxiety attack or general pain [102]. This integration helps individuals modulate their sensory experiences while promoting security [103, 104].

Should the distress persist, the system transitions to the second stage, alerting parents and caregivers if distress persists beyond a certain threshold. This immediate notification empowers them to respond promptly and offer personalized support tailored to the child's emotional needs.

Simultaneously, the future versions of HealPet will equip children with various emotional coping exercises as they wait for parents and caregivers. These exercises, ranging from mindfulness practices to relaxation techniques, are meant to be practiced and mastered by both the child and their guardians, catering to their unique emotional needs. From guided deep-breathing exercises and visualization techniques to interactive storytelling that promotes emotional expression, the toy would enable young patients to develop and master practical coping strategies.

8.2.1 The HiLetgo GD3300 UART

The HiLetgo GD3300 UART Control Serial MP3 Music Player Module was used in toys that aim to support mental well-being [105]. This compact module is designed for integration into electronic systems, allowing seamless communication with microcontrollers and other devices through its UART interface [106], enabling precise control over audio playback functionalities [107]. The GD3300 module delivers audio feedback, prompts, and therapeutic support in toys focused on monitoring health [108]. (see Appendix VIII)

8.2.2 The Feetech FS90R Micro Continuous Rotation Servo Analog Motor

When paired with an RC tire wheel, the Feetech FS90R Micro Continuous Rotation Servo Analog Motor provides a solution for incorporating calming features into a toy to comfort children dealing with distress or anxiety. This servo motor, capable of rotating 360 degrees, allows control over the wheel's movement to deliver vibrations effectively [109]. When integrated into a toy like an animal or interactive device, the FS90R servo motor can be programmed to activate a soothing mode in response to identifying signs of unease or anxiety in the child [110].

In upcoming models, the smart toy will come equipped with sensors such as heart rate monitors and oximetry devices, including galvanic skin response sensors or voice recognition microphones capable of analyzing vocal cues related to stress, like crying, to identify distress or anxiety. The intelligent toy triggers the soothing mode once these sensors pick up on heightened stress levels or other discomfort indicators. This mode prompts the FS90R servo motor to engage the gears, causing the attached wheel to vibrate gently. The vibrations produced by the servo motor provide tactile stimulation that encourages relaxation and diminishes stress levels in children [111].

The technical details of the Feetech FS90R servo motor include its operational voltage range, from 4.8V to 6V, which makes it compatible with power sources like AA batteries or rechargeable packs. Running at a speed of 110 RPM (Rotations Per Minute) at 4.8V, this motor provides consistent movement, ensuring a calming experience for children. Its small size and lightweight allow it to be easily integrated into types of toys without compromising their looks or functionality.

Incorporating the Feetech FS90R servo motor into a toy designed to comfort children showcases an application of robotics and sensor technology in pediatric care. The intelligent toy can deliver personalized and adaptive support to children facing distress or anxiety by combining sensors with motor control. Furthermore, utilizing tactile stimulation aligns with proven healthcare practices that emphasize the importance of multisensory approaches in promoting relaxation and emotional well-being in children [112].

Future versions of HealPet will feature pressure stimulation and LED lights. The current JITAI intervention model involves playing music using the HiLetgo UART, using vibration motor stimulation, and notifying parents/caregivers about alerts.

In this way, the toy enhances emotional well-being by providing real-time alerts for parents and engaging in coping exercises for the child. It supports the patient and empowers both the child and caregivers to tackle emotional challenges together, strengthening their support network.

8.3 Key Usage

Here is a table that outlines some key usages for HealPet. It shows how the toy detects and reacts to a child's emotions or physical pain, in situations linked to cancer and chronic pain.

Table 9: Key HealPet Usage Examples

Scenario	**What the Toy Senses**	**How the Toy Responds**
Anxiety Before a Medical Procedure (Cancer Patient)	Heart rate increases, oxygen levels slightly decrease due to heightened anxiety before chemotherapy.	HealPet plays calming music and emits gentle vibrations to soothe the child. Additionally, it provides feedback to parents or medical staff,

		alerting them to the child’s distress, prompting additional support if needed. Future versions engage with the child in comforting conversation or suggest a breathing exercise to reduce anxiety.
Emotional Distress During a Pain Flare-Up (Chronic Pain Patient)	The child grips the toy tightly, and erratic movements are detected due to pain.	HealPet activates soothing sounds and vibrations to distract the child. Future versions may offer interactive suggestions like, "Would you like to play a game?" to divert the child’s attention. The toy logs the event for caregivers or clinicians to track pain episodes, helping them adjust the child's pain management plan.
Nighttime Anxiety During Hospital Stays (Cancer Patient)	Heart rate increases at night, indicating anxiety or fear while sleeping in an unfamiliar hospital environment.	It plays a lullaby or emits a soft light to make the child feel secure. If the child’s anxiety persists, the toy can alert hospital staff or parents, suggesting that further intervention may be needed to ensure the child’s comfort. In future versions, HealPet responds by softly speaking comforting phrases like, “I’m here with you” or “You’re safe.”
Detecting Stress During Physical Therapy (Chronic Pain Patient)	Erratic, jerky movements and elevated heart rate are detected during physical therapy.	HealPet initiates calming feedback through vibration or soothing music. The collected data can be used by the physical therapist to adjust treatment based on the child’s emotional state. Future versions offer gentle encouragement like “You’re doing great!” while also suggesting taking a short rest or engaging in a fun activity or breathing exercise to help the child relax before continuing therapy.
Emotional Distress During Treatment Waiting Period (Cancer Patient)	Restlessness and increased heart rate detected while waiting for treatment.	Healpet plays music/lullabies while they wait. If the child's anxiety increases, the toy can notify a parent or medical professional to step in with additional support. Future versions of HealPet will activate a calming intervention, such as asking the child if they want to hear a story or participate in a distraction activity to pass the time.

9. Prototypes and Electronics Analyses

9.1 Prototypes

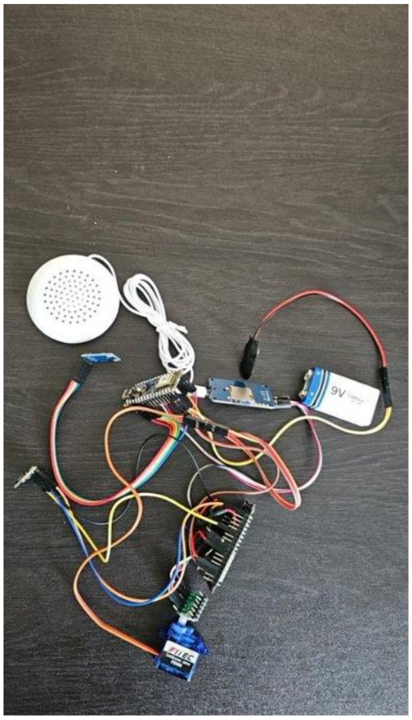


Figure 5: Prototype

The first prototype was assembled utilizing the components described in the previous paragraphs. Data collection went as expected, but the prototype had a few key limitations regarding power, data frequency, MP3 volume, and data transmission.

The first prototype was created to establish core functions; however, it encountered significant challenges concerning power supply issues and data transmission & sound output problems. Utilizing the Arduino Nano initially posed limitations in powering the toy's machinery and sensors hence changes were made to the more robust Arduino Uno in subsequent versions. Aside from this, the operating frequency didn’t reach the minimum threshold of some pins (12 pins per second) which caused inefficiencies in the module given that the chip was overloaded with data. The Arduino Nano didn’t have sufficient VCC and GND pins, which could have been resolved by coding more pins but would have caused more instability. This takes away from the power and efficiency as it must be set automatically when used on multiple occasions. The Arduino Uno offers multiple GPIO pins and higher processing capability, necessary for multiple sensors and modules. This modification brought forth enhanced reliability and facilitated management of diverse tasks, like motor operation and data capturing.

The second version aimed to enhance clarity and storage capacity by incorporating a small speaker which notably boosted the volume for MP3 playback. Tackling a primary concern highlighted in the initial iteration. Additionally facilitating data transfer with an SD card offered a temporary fix for connectivity troubles but was deemed suboptimal for extended usage due to the need for frequent manual file transfers.

The third model upgrade brought enhancements to the toy's functionality and convenience level by switching from a 9-volt battery to 4 AA batteries which boosted the battery life from 10 to 40 hours of continuous use, making it more suitable, for daily use purposes. Moreover, wireless data transmission was successfully enabled for Android devices in this version; iOS compatibility with Thunkable (a third-party application) continued to pose difficulties.

Despite these progressions in technology and innovation, there were still some constraints to address. The precision of the sensors especially when tracking heart rate and oxygen levels needed further enhancements. Variations in data due to movement and sensor positioning posed challenges for maintaining monitoring. In the versions the customization options tailored to specific health conditions were not fully developed. These persistent difficulties have shown opportunities for enhancement that will be tackled in advancements.

9.2 Prototype Stuffed Animals

Four plush toys were chosen (Appendix II) to house the hardware: a pink dragon, a blue dragon, a penguin, and a unicorn. These toys were chosen due to their similarity to our 3D models, ensuring a consistent and appealing choice for children. The pink dragon has vibrant colors, shiny silver wings (glitter) and a friendly expression. The blue dragon captivates with its bright hue and intricate scales. The penguin charms with its timeless and black and white appearance and cuddly round shape accentuated by a cheery orange beak. The unicorn toy is designed with a white body and a colorful-rainbow mane, hooves that shimmer in pink glitter and a golden horn on its head. The presence of a zipper underneath in all 4 toys gave easy access to the interior, making them suitable for sensor integration. We made sure the sensors were all firmly glued to each other so they wouldn't move during agitated play, and that they wouldn't come out due to safety requirements. The only sensor that was left outside the zipper was the MAX30102 as it requires direct skin contact to provide data readings.

9.3 Electronics Analyses

9.3.1 Current

To calculate the current required by HealPet, we can use the formula:

$$I = \frac{C}{t}$$

Where:

- I is the current in milliamperes (A)
- C is the total battery capacity in milliamperes-hours (mAh)

- t is the time the device operates in hours (h)

However, since we only know the battery life and not the power directly, we need to estimate the power consumption first. The energy provided by the batteries can be calculated using their capacity, typically measured in milliampere-hours (mAh).

Knowns:

- A typical AA battery has a capacity of about 2000 mAh.
- 4 AA batteries provide a total voltage of 6V (since each AA battery provides 1.5V).

Calculate Battery Capacity

$$C(total) = 200mAh \times 4 = 8000mAh$$

Calculate Current Drawn

The toy lasts for 40 hours, so the current drawn can be calculated as:

$$I = \frac{8000mAh}{40\ h} = 200mA$$

Therefore, the HealPet toy requires a current of 200 mA or 0.2 A.

9.3.2 Power Consumption

To calculate the power consumption of HealPet, we can use the following formula:

$$P = VI$$

Where:

- P is the power in watts (W),
- V is the voltage in volts (V),
- I is the current in amperes (A).

Knowns:

- V = 6 V
- I = 200mA = 0.2A

Calculation:

$$P = 6V\ (0.2A)$$

$$P = 1.2W$$

So, HealPet's power consumption is 1.2 watts.

Based on the technical breakdown provided in your thesis document, let's dive into a more detailed technical analysis of HealPet's electronic design and components. This analysis will align with the power consumption and overall functionality that we previously calculated.

Core Components:

Arduino Nano 33 BLE Sense Rev 2:

Microcontroller: ARM Cortex-M4 CPU @ 64 MHz.

Power Consumption: Estimated at 10-50 mA depending on the activity.

ESP-WROOM-32 ESP32 Development Board:

Microcontroller: Dual-core Tensilica LX6 @ up to 240 MHz.

Power Consumption: Approximately 50-150 mA depending on wireless communication and processing tasks.

Sensor Power Consumption: MAX 30102 (1-5 mA), Accelerometer (0.3-0.5 mA)

Actuator Power Consumption: Vibration Motor (100-200 mA), LED Lights (10-20 mA)

Actuators and Output Devices:

HiLetgo GD3300 UART Control Serial MP3 Music Player Module:

Power Consumption: Dependent on volume and usage, estimated at 20-50 mA.

Vibration Motor (Feetech FS90R)

Power Consumption: Estimated at around 100-200 mA depending on the intensity of vibrations.

LED Lights:

Power Consumption: Typically, 10-20 mA depending on brightness and usage.

Energy Management:

Sleep Mode:

To save power, the microcontroller enters a low-power sleep mode when the toy is inactive, reducing current draw to a few microamps.

Data Transmission:

Wireless Communication:

- The ESP32 board handles data transmission to external devices (like a caregiver's smartphone), allowing remote.
- Power Consumption: Wi-Fi/Bluetooth communication is one of the higher power-consuming activities, estimated at 80-150 mA during transmission.

monitoring

Operating Time and Power Budget:

Microcontroller: 10-50 mA

Sensors: 1-10 mA

Actuators/Outputs (Motor, LEDs, Speaker): 130-270 mA

Total Estimated Current: 150-330 mA (depending on activity)

Battery Life Estimation: With a draw of around 200 mA, the battery life aligns with the 40-hour operational time calculated earlier, confirming the toy's power efficiency.

Heat Management:

Given the low power consumption (1.2W), heat dissipation should be minimal, but proper ventilation in the toy's design can help prevent any potential overheating, particularly around the microcontroller and communication modules.

10. Software and System Calibration

10.1 Programming

Programming of the sensors was done using Arduino IDE as shown in the Appendix 4 code. One of the main obstacles faced was compressing the precision of the data because Arduino didn’t have enough flash memory. Flash Memory is where Arduino sketch (program) is stored and both the Arduino Nano and Uno have 32 KB of flash memory. Both Arduino boards offer 2 KB of SRAM which is used for storing variables when a program runs. It's where sensor data, variables, and intermediate computations need to fit.

The main issue with memory is running out of SRAM. Complex calculations and large libraries can fill up SRAM, which can lead to crashes or unwanted behavior. Complex calculations and large libraries can fill up the SRAM, leading to crashes or unwanted behavior. We converted some float64’s to float32’s and some float 32’s to int, until SRAM use went from 130% to 98%, freeing up SRAM. The Arduino onboard storage is usually just the flash memory used for storing the code. It was insufficient for data logging or storing large amounts of data, so we integrated an SD card module to store large amounts of data and used it for the prototype stages instead of the Bluetooth module which also had a larger power consumption and didn’t work for IOS phones. Voice recognition code needs a larger SRAM for high-speed calculations and can be obtained by using an Arduino Mega instead.

We also optimized battery life with sleep modes, reducing the sampling rate, and using power-efficient libraries. RTOS (Real-Time Operating System) or an event-driven architecture were used to ensure real-time processing and responsiveness of the system. To ensure reliability when a sensor fails or data is corrupted, we use watchdog timers and in future steps we will also incorporate error logging to non-volatile memory, and recovery routines.

10.2 Parameters

It is important to reiterate that all testing at this phase is meant to ensure the accuracy of the sensors in a controlled lab setting and to test its interconnection to the intervention system rather than to diagnose or detect ill health. We started by researching the accepted healthy values for a child aged 2-8 years old. The following table illustrates such values:

Table 10: Normal Values [113]

Age	BPM	SPO2	Daily Steps
2-3	80-130	95-100	5,000-8,000
3-6	75-120	95-100	8,000-10,000
6-8	70-110	95-100	10,000-12,000

Since the majority of the children in the testing group will lie between the ages of 3-6, we will set the triggering parameters to 110 bpm and 96.5% heart rate, and keep track of the daily steps especially when they go below 7,000. Detection of crying could, for instance, trigger the device to deliver a just-in-time adaptive intervention to soothe the child.

10.2.1 Trigger Values

The trigger values to determine whether a child was suffering from anxiety and deploy the JITAI response were set as follows:

Table 11: Trigger Values

Heart Rate	Oxygen Saturation
120bpm	97%

These parameters were set at a value that would apply for all the children tested.

10.3 Data Processing

It is challenging to pinpoint emotions by relying on proprioceptive sensor data since emotions are intricate and involve various aspects, like physiology, cognition, and behavior. Nevertheless, our goal is to create a system that can recognize patterns linked to emotional states through the following approach:

1. Gathering Data: We will collect data from movement and pressure sensors while observing how a child interacts with the toy. For instance, when the child squeezes the toy, we obtain sensor data indicating changes in pressure and possibly movement.

2. Defining Emotional Indicators: We will look for features or patterns in the sensor data that may correspond to emotional states. For example, we will consider factors like the intensity and duration of pressure applied to the toy, the frequency of squeezes, and how these patterns evolve.

3. Training with Data: We will gather data from children experiencing emotional states while engaging with the toy. Our machine-learning algorithm will use this information as labeled training samples. Additionally, we will ask children to self-report their emotions (with assistance from ECGs in future steps for verification) during these interactions to establish labels based on their experiences.

4. Utilize a machine learning model, such as a classification algorithm or neural network, to help understand how sensor data patterns relate to states. The features extracted from the sensor data may include measures like values, variability, or more intricate patterns derived from signal processing techniques.

5. To ensure the model's accuracy, divide the collected data into training and testing sets. Train the model with the training data. Evaluate its performance using metrics like precision, recall, and F1 score on the testing data. This will help gauge how well the model can predict states based on sensor data.

6. Recognizing that emotions evolved, consider implementing a system for the model to continually learn and adapt to data. Regular updates to the model based on labeled data can enhance its capabilities.

7. It is crucial to analyze the model's predictions within their interaction context. For example, a hug might signify happiness if accompanied by laughter and playful behavior. It could indicate anxiety if paired with signs like restlessness or a rigid stance.

Identifying emotions through interactions with a toy can be challenging since various factors like personal feelings, surroundings, and mental processes shape emotions.

Handling these assessments correctly and viewing them as an aid rather than a concrete way to gauge emotions is essential. This process was started for the audio detection but didn't obtain sufficient data to create a robust data pool for predictions. An audio detection machine learning model and an overall adaptive, emotional machine learning algorithm with accurate data (verified with ECGSs) are listed as part of the next steps of these projects.

11. Testing and Results

11.1 Testing procedure

Testing was done in accordance with IRB protocols and standards, and consent was obtained from all participants. Compensation was given in the form of a $20 gift card per family plus a book to every child participant. Parents and children were given the IRB approved consent form and the study as well as its goals were thoroughly explained before the start of the testing.

At this stage, 4 full working sensor prototypes had been completed and incorporated into the stuffed animals that we bought online as shown in Appendix II. The children were encouraged to name them so that the interaction was more personalized.

11.1.1 User Recruitment

User recruitment involved posting flyers around the Dartmouth campus and Upper Valley region which spans 27 towns between New Hampshire and Vermont. We also reached out to people in specific programs such as Tuck School of Business to disseminate information through social media.

11.1.2 Testing Objectives and Rationale

The evaluation process for the HealPet product was meticulously planned to investigate the research questions (as defined on the introduction) regarding its efficacy as a tool for monitoring and supporting emotions in children dealing with chronic illnesses.

One of the main objectives of the evaluation was to ascertain the toy’s capability in identifying distress in children through the utilization of sensors. The toy underwent testing in controlled as well as real-world environments to evaluate its effectiveness in delivering immediate calming responses such as music or vibrations upon detecting signs of distress. The testing phase of the study focused on identifying some straightforward signs of emotional distress through physiological and behavioral cues such as heart rate monitoring and movement patterns analysis. This data will also be used to make future machine learning models.

The experiments also looked into how receiving emotional comfort from HealPet could improve the well-being and mental state of children when they feel anxious or upset. The plush toy was created to react to such situations by providing support. Subsequently, we evaluated the therapeutic effects of HealPet through surveys for children and their families to determine how comforting the toy was perceived to be and if it had a positive impact on monitoring children's emotional well-being. We also sought feedback from parents regarding the toy's ease-of-use in activities and its effectiveness in offering emotional assistance, which will prove invaluable for enhancing the toy's design.

For this initial testing phase, the objectives were not focused on assessing, diagnosing or treating children, but rather to evaluate sensing performance of the device and gather data on the user experience. The intent was to demonstrate that the toy was functional and accurately measured the signals of interest. Furthermore, we wanted to see how children responded and their feedback as well as parental feedback.

11.1.3 Procedures

User studies were performed in the Empower Lab space. Healthy children were tested during this phase of the study. They were each handed a toy and allowed to play freely in the presence of their parents. The testing ended whenever the parents deemed their children appeared to be distracted or when 30-45 minutes had passed since the start of the test.

11.1.4 Observational Findings

The 4 prototypes were utilized simultaneously, when possible, while testing children in groups of 3. We noticed that this was a success because children were more inclined to play for longer periods if they had peers to play with. This finding was meaningful because it indicated that these toys encouraged group play and socialization as expected. The children were also more likely to play if they had their own toys as they could alternate between playing with their own toys and the toys provided by the study.

11.2 Data Collection and Sensory Analysis

11.2.1 User Demographics

A total of 9 males and 6 females participated in the testing phase, however the results for the first child served as a means to calibrate and set the trigger parameters as well as fix internal issues with the connections. The relevant data utilized for analysis corresponded to 8 males and 6 females; 5 Asian and 9 white children.

11.2.2 Summary Statistics

Age

Mean: 9.88 years

Standard Deviation: 2.92 years

Range: 2 to 13 years

Heart Rate (bpm):

Mean: 93.63 bpm

Standard Deviation: 11.28 bpm

Range: 70 to 110 bpm

Oxygen Level (%):

Mean: 97.97%

Standard Deviation: 0.12%

Range: 97.63% to 98.23%

Moving Frequency (per min):

Mean: 22.55 movements per minute

Standard Deviation: 11.70 movements per minute

Range: 6 to 48 movements per minute

Max Move Speed (m/s):

Mean: 1.71 m/s

Standard Deviation: 0.74 m/s

Range: 0.33 to 3.00 m/s

Steps:

Mean: 568

Table 12: Statistical Analysis

	Age	Heart Rate (bpm)	Oxygen Level (%)	Moving Frequency (per min)	Max Move Speed (m/s)
count	292	292	292	292	292
mean	9.876712329	93.62671233	97.97126712	22.55136986	1.710856164
std	2.915512277	11.27724828	0.116990192	11.70370597	0.742437441
min	2	70	97.63	6	0.33
25%	5	83.75	97.9	12.75	1.18
50%	10	95	97.985	19	2.02
75%	13	104	98.05	29	2.21
max	13	110	98.23	48	3

Age-wise Analysis

Key Insights:

Heart Rate:

The heart rate is higher in the 11-13 age group compared to the younger age groups.

Oxygen Level:

Oxygen levels are relatively stable across all age ranges.

Moving Frequency:

Higher in the youngest age group (2-7), decreases in the 8-10 age group, and slightly increases again in the 11-13 age group.

Max Move Speed:

The highest in the 2-7 age group, lower in the 8-10 age group, and slightly higher in the 11-13 age group.

Table 13: Statistics summary

Age Range	Heart Rate (bpm)	Oxygen Level (%)	Moving Frequency (per min)	Max Move Speed (m/s)
2-7	90.24	97.99	31.57	2.08
8-10	91.84	98.01	15.73	1.19
11-13	102.61	97.96	20.78	1.95

Trend Analysis

Heart Rate Trend:

Each line represents a different child, showing how their heart rate changes over time.

Moving Frequency Trend:

Similarly, each line represents a different child, showing changes in their movement frequency over time.

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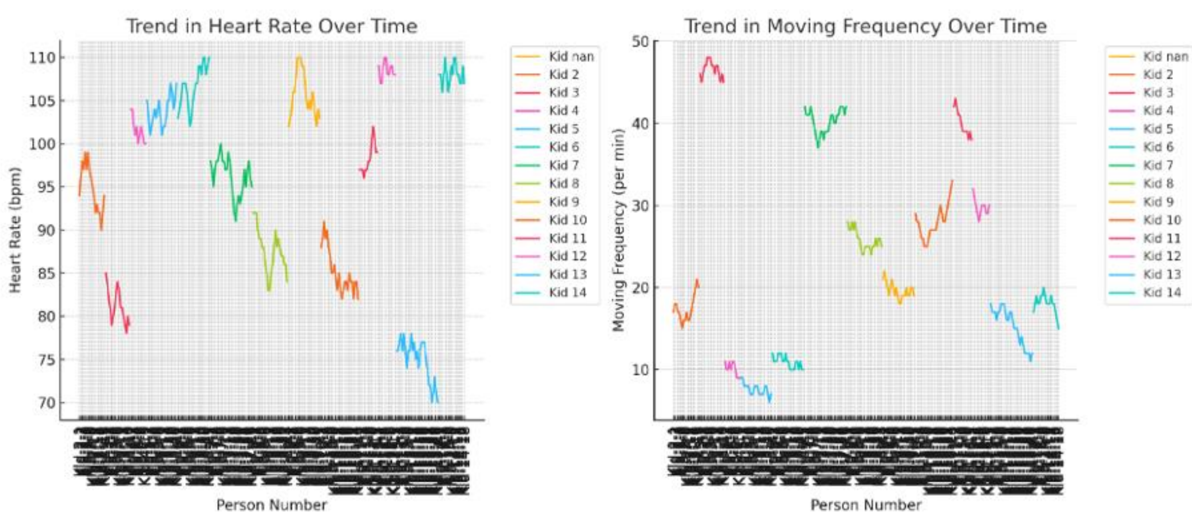


Figures 6,7: Heart rate and moving tendencies over time

11.2.3 Heart Rate and Oxygen Level Distribution

For initial comparison purposes, we used a clinical grade pulse oximeter to check if data was reliable in pre-testing environments. We tested under different scenarios (movement, stress, relaxed state).

Bland-Altman Analysis:

Collect Data:

- Record paired measurements from both the MAX30102 and the clinical-grade pulse oximeter. Let's denote these as $X_M$and X_P for MAX30102 and clinical-grade pulse oximeter respectively.

Calculate the Differences:

- Calculate the difference between each pair of measurements:

$$Dif_i = X_{M_i} - X_{P_I}$$

- Calculate the average of these differences (mean dif):

$$Mean\ Dif \ = \frac{1}{n}\sum_{i=1}^{n} Dif_i$$

- The mean difference represents the bias between the two devices.

Calculate the Average Measurements:

$$Avg_i = \frac{X_{M_i} - X_{P_I}}{2}$$

- For each pair, calculate the average of the two measurements:

Calculate the Limits of Agreement:

- Calculate the standard deviation (SD) of the differences:

$$SD = \sqrt{\frac{1}{n-1}\sum_{i=1}^{n}(Dif_i - Mean\ Dif)^2}$$

- Calculate the limits of agreement, which are typically set at ±1.96 times the SD:

$$Lower\ Limit\ =\ Mean\ Dif\ -\ 1.96 \times SD$$

$$Upper\ Limit\ =\ Mean\ Dif\ +\ 1.96 \times SD$$

Bland-Altman Plot:

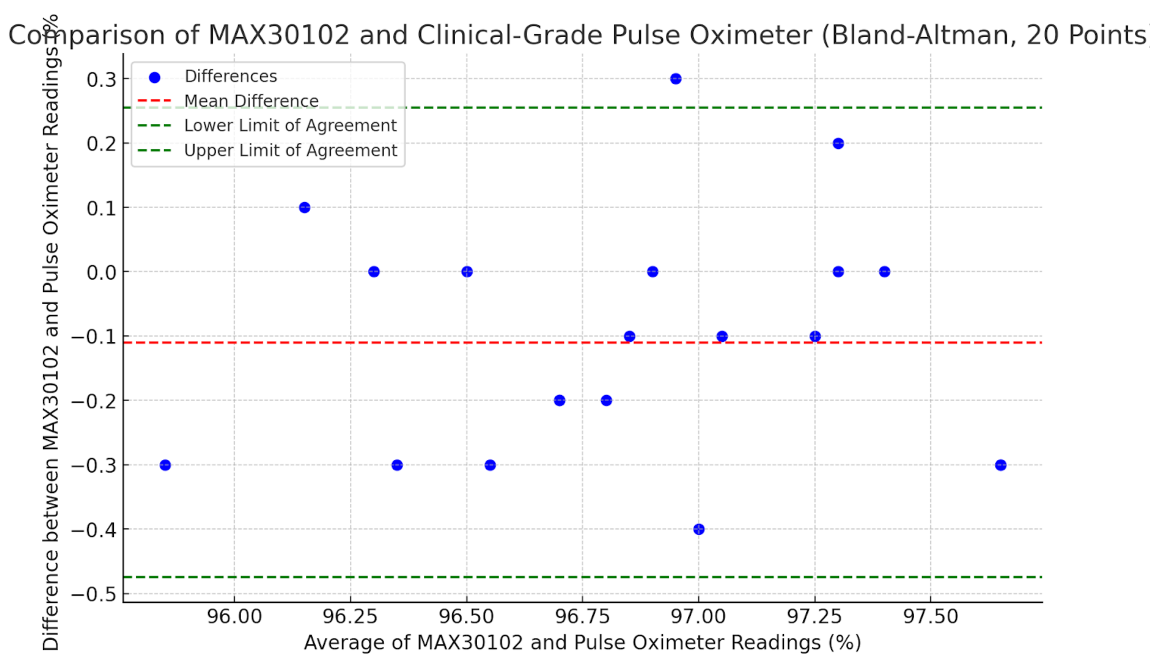


Figure 8: Bland-Altman Plot

Small-Scale Validation

- Mean Absolute Error (MAE): 0.17%
- Mean Difference (Bias): -0.11%
- Lower Limit of Agreement: -0.47%
- Upper Limit of Agreement: 0.25%

These results suggest that, on average, the MAX30102 sensor reads slightly lower than the clinical-grade pulse oximeter by about 0.11%. The limits of agreement indicate that the differences between the two devices mostly fall within the range of approximately -0.47% to 0.25%. The mean difference of -0.11% indicates that, on average, the MAX30102 readings are slightly lower than the clinical-grade pulse oximeter readings, but the bias is very small.

Heart Rate Distribution:
The histogram shows the frequency of different heart rate values across all the data. Most of the heart rates are clustered around 80-100 bpm.

Oxygen Level Distribution:
The histogram illustrates the distribution of oxygen levels. Most oxygen levels are tightly clustered around 97.9% to 98.0%, indicating very little variation.

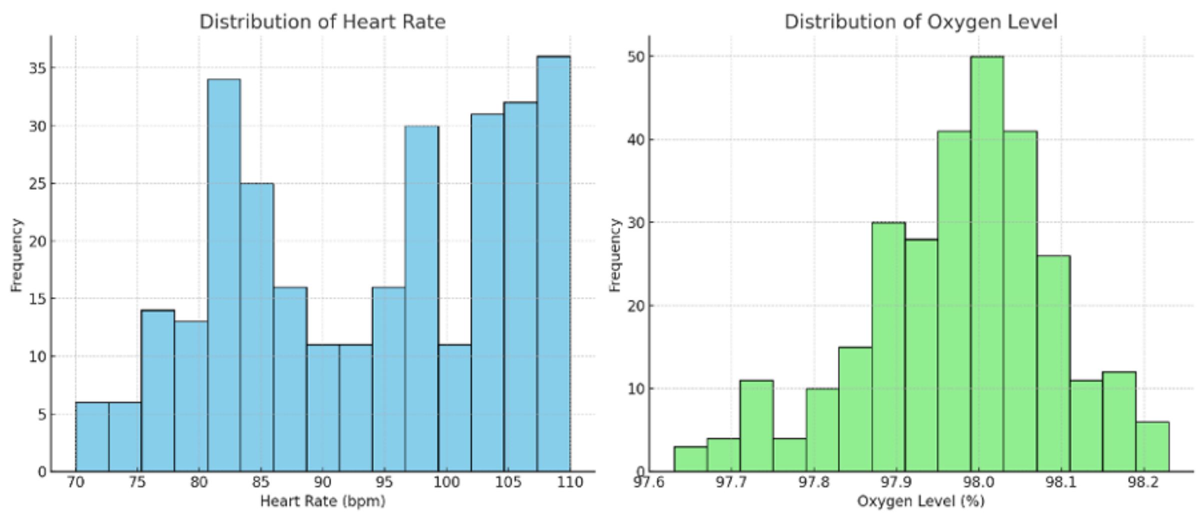


Figure 9,10: Distributions of heart rate and oxygen levels

11.2.4 Summary of Quantitative Results

Statistical Analysis

The statistical analysis of the results was completed based on the extracted data from the sensors following the previously established parameters. The toy effectively tracked physiological signs (heart rate and oxygen levels).

Overall Insights:

- Effective Monitoring: HealPet successfully tracked physiological signs such as heart rate and oxygen levels, showing reliable and consistent data across different children.
- Tailored Responses: The diverse physiological responses recorded emphasize the need for personalized interaction and responses by HealPet to suit individual children's needs.

Heart Rate Trends:

- Variation Across Age Groups: Older children (11-13 years) tend to have higher heart rates compared to younger children, which could indicate varying stress or activity levels.

- Distribution: Most heart rates are clustered between 80 and 100 bpm, with the average at 93.63 bpm, indicating a healthy range across the group.

Oxygen Levels:

- Stability: Oxygen levels remained stable across all age groups, with a very narrow distribution around 98%, suggesting consistent monitoring and no significant respiratory issues in the sample group.

Movement Frequency and Speed:

- Age-Dependent Activity: The youngest children (2-7 years) showed the highest movement frequency and speed, which decreased in the 8-10 age group and slightly increased again in older children.
- Activity Insights: Average movement frequency was 22.55 movements per minute, with noticeable variations highlighting different activity levels and potentially emotional states.

11.3 Surveys/Qualitative Approach

The survey results demonstrated that 11/15 of children were feeling happy when they went into the test. Favorably, at the end of the test 13/15 of the children were happy after their interaction with the toy. Most children reported the glitter being their favorite quality of the pet, but also enjoying the big wings as well as the texture and pattern of the toys. 12/15 of the children and families reported that using the smart toy was easy. 13/15 of children also reported wanting to play with the toy again. 11/15 children reported that the JITAI (music and vibrational stimulus) were helpful. The main thing that they suggested changing was enabling HealPet to talk to them since they wanted more interactivity or a more personalized experience. Some children suggested giving each toy a name and others also reported not liking the dinosaur's antlers and preferring it to have ears.

Table 14: User Feedback

Aspect of User Experience	Details	Examples
Child Interaction and Engagement	● Children were generally happy before and even more so after the test. ● Enjoyed specific features of the toy such as glitter, wings, texture, and pattern. ● Found the toy easy to use. ● Wanted to play with the toy again. ● Found JITAI (music and vibrational stimulus) helpful.	"I felt happy playing with the toy." "I love the pink dragon's glitter! "I love the blue dragon's wings!" "It's easy to play with." "Can I play with it again?" "The music and vibrations helped me feel better."
Parental Observations and Feedback	● Parents observed positive interactions between their children and the toy. ● Noted improvements in their children's mood and behavior.	"My child seemed more relaxed and happy." "It's great to see my child enjoying something."
Usability and User Experience	● Most found the toy easy to use. ● Positive feedback on user experience from both children and parents.	"The toy is very fun to play with." "We were playing with it together."
Impact on Well-Being	● Changes in children's behavior and mood noted after using the toy. ● Toy has potential to enhance well-being of children.	"He seems much happier after playing with it." "It's a helpful distraction."
Areas for Improvement	● Desire for more interactivity, such as the toy talking. ● Suggestions for giving each pet a name. ● Preference for ears instead of antlers on the dinosaur toy.	"It would be cool if the toy could talk to us." "Can we name the toy?" "I don't like the antlers; ears would be better."

Customizing Toys to Meet Individual Needs

During interviews the importance of tailoring the toy to each child's needs was noted. This led to the integration of sensors that can track heart rate, oxygen levels and movement. These sensors were tuned using age data from insights in Tables 6 and 10 to ensure the toy could effectively respond to each child's emotional and physical condition. User studies confirmed the effectiveness of these design decisions by demonstrating how children's interactions with the toy provided information for customizing its responses.

User Friendly Design and Acceptance

Therapists stressed the importance of making the toy engaging and non-invasive. This feedback prompted enhancements in the toy's appearance making it more attractive and user friendly. The final prototypes featured elements like glitter, wings and textures that children found appealing. Results from user studies indicated levels of acceptance with children expressing eagerness to play with the toy again due to its ease of use.

Affordable Solutions without High Tech Components

The goal of achieving a low-cost solution was accomplished by opting for components like Arduino Nano and later Arduino Uno. These components offer a balance between affordability and functionality, for meeting the toys requirements. The prioritization matrix and cost analysis sections were carefully considered to make sure the toy is affordable.

By combining insights from interviews with the project's requirements and limitations, the design and development of the toy followed a framework to ensure the end product was efficient and practical. The process of creating prototypes guided by feedback from both clinical experts and users emphasizes the significance of a flexible design approach, in developing therapeutic tools that promote children's mental and emotional well-being. Users expressed satisfaction, offering ideas for enhancements, like incorporating voice commands and personalized features. The design implications confirm the specifications and limitations proving that a research-based user focused design can truly promote soothing of children.

12. Discussions

12.1 Evaluation

Based on the defined needs and completed work we determined what was accomplished and what areas could use more work. The following table is derived from Table 3, Criteria and Constraints; to put a numerical value to measure to what degree benchmarks were fulfilled and what areas need improvement.

Table 15: Evaluation of Benchmarks

Criteria/Objective	Metrics/Benchmarks	Evaluation and Score (1-5)
Customization for individual children	- Availability of personalized settings/options - ML models adaptation onto track emotions, behavioral patterns and physiognomy	**In Progress**: Initial settings developed, but full range of options not yet available. (Score: 2/5) **Not Yet Started**: Machine learning adaptations for long-term monitoring are in the planning phase. (Score: 1/5)
Customization for specific diseases	- Disease-specific customization options - Preliminary feedback from clinicians on disease-specific utility - Responsiveness to treatment phases	**In Progress**: Some disease-specific customizations implemented, but additional development is required. (Score: 2/5) **Partially Met**: Feedback indicates initial success, but comprehensive disease-specific utility is not yet achieved. (Score: 3/5) **Not Met**: Further development needed to ensure the toy's responsiveness to different treatment phases. (Score: 1/5)
Acceptability and Ethics	- User satisfaction scores (children, parents, clinicians) - Time taken to learn/use interface (less than 5 minutes) - Privacy compliance based on initial design	**Exceeded**: User interface and engagement have surpassed expectations with very high satisfaction scores. (Score: 5/5) **Met**: Less than 5 minutes learning curve. (Score: 4/5) **Met**: Initial design aligns with IRB and privacy guidelines. (Score: 4/5)
Low Tech/Affordability	- Estimated production cost per unit (less than $55) - Expected retail price vs. average income brackets - Preliminary material quality assessments	**Met**: Production cost and affordability targets have been successfully achieved, aligning with the project's goals. (Score: 4/5) **Met**: Affordable expected retail pricing. (Score: 4/5) **Partially Met**: Positive initial material assessments. (Score: 3/5)

Grounded in Scientific Approach	- Correlation with expected clinical monitoring data (based on healthy child data) - Initial clinician feedback on potential utility - Short-term data retention and accuracy - Initial feedback from parents and clinicians on monitoring capabilities	**Partially Met**: Initial scientific approaches are promising, with some correlation data collected, but further testing and validation are needed. (Score: 3/5) **Partially Met**: Positive initial feedback from clinicians, but full validation is pending. (Score: 3/5) **Met**: Short-term data retention and accuracy have been achieved, indicating potential for long-term monitoring. (Score: 4/5) **In Progress**: Initial feedback is promising, but long-term monitoring systems are still in development. (Score: 2/5)
Safety and Comfort	- Preliminary safety and comfort feedback from users - Observation of material response during short-term usage	**In Progress**: Passed IRB testing standards, but comprehensive safety testing (e.g., ISO standards) is still pending. (Score: 2/5) **In Progress**: Material response is favorable in short-term use, pending long-term evaluations. (Score: 2/5)
Emotional Engagement and Soothing	- Emotional engagement scores from initial user tests - Preliminary effectiveness of sensory feedback (measured through short-term child response) - Initial user engagement	**Met**: Emotional engagement and soothing features are performing well in initial tests, achieving high levels of user satisfaction. (Score: 4/5) **Met**: Preliminary sensory feedback is effective in reducing anxiety levels. (Score: 4/5) **Met**: High user engagement in short-term use. (Score: 4/5)

Based on these results and evaluations, the next two sections (Limitations and Future Steps) will delve deeper into the changes that must be made to improve HealPet particularly in the areas of sensor accuracy, customization for individual children, customization for specific diseases and acceptability. The discussions for safety and material choices can be found in Appendices VI and VII, respectively.

12.2 Limitations

Sensor Accuracy: The accuracy of sensors like heart rate monitors, oxygen levels, and motion sensors can vary. Environmental factors, sensor placement, and individual differences in children may affect the precision of data collected. These factors are discussed in detail below.

a. Placement and Movement: The accuracy of the heart rate monitor can differ depending on where it's positioned on the body. For example placing the sensor on the wrist may provide better measurements than placing it on the chest because of its continual contact with the skin. Children moving around or performing any kind of abrupt physical activity can alter the data, showing spikes or dips in the heart rate readings.
b. Personal Routines: behaviors like being restless or how a child interacts with a toy can influence the accuracy of the gathered data. A child who frequently adjusts the toy might accidentally shift the sensors impacting the consistency of the measurements.

Motion Sensors:

Physical Activity: The reliability of motion sensors may be influenced by a child's activity. Engaging in high energy activities like running or jumping can lead to increased sensor noise making it difficult to differentiate between unusual movement patterns.

Individual Differences

Unique physiological and behavioral distinctions among children can also impact sensor accuracy. Factors such as skin type, body composition and personal habits should be taken into account when assessing sensor performance.

Skin Type and Body Composition: Differences in skin type (like dry skin) and body composition (such as body fat percentage) can affect how well the sensors stick to the skin

and record precise information. For instance sensors may struggle to stay in place on skin leading to data interruptions.
The challenges related to sensor precision in toys emphasize the need for improvement and adjustment.

Data Interpretation: The interpretation of physiological and behavioral data to accurately assess mood can be challenging. Correlating sensor readings with specific emotional states requires robust validation.

MAX30102 location: In the prototype, the MAX30102's location was uncomfortable and not intuitive. The sensor will be re-positioned in a place where the child naturally holds the toy, allowing for a more natural interaction. Furthermore, lights and movement can be added to attract the child's attention. For example, the toy's hand can pulse gently with light or have a soft vibration, and thus ensure consistent sensor contact.

12.3 Prototype changes

3D printing:

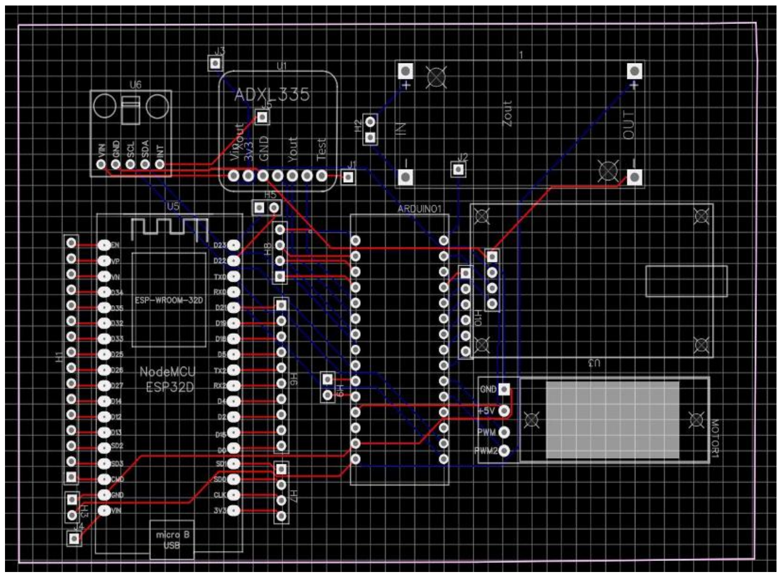
As mentioned in the 3D printing section, the designs can be improved by making them specifically for the 3D printer.

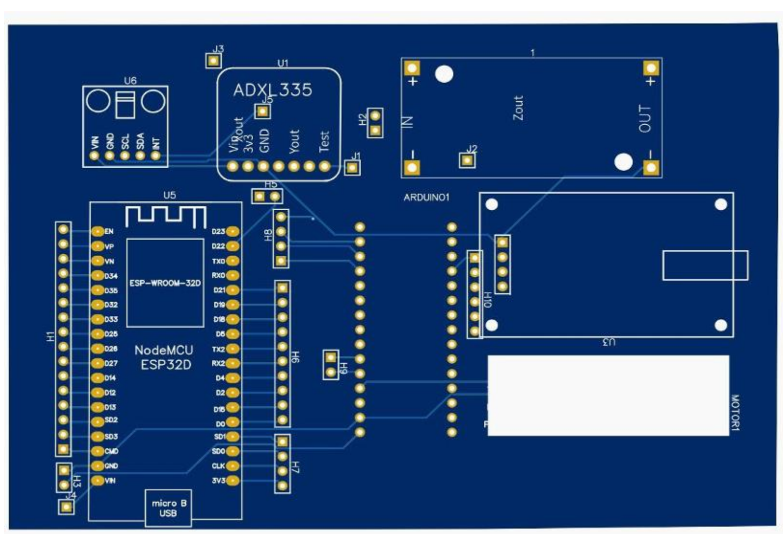
Stuffed Animals:

Stuffed animals will later be created utilizing the blender designs and adapting them for hand-made prints of the fabric that can be sowed and stuffed with cotton. Subsequently, such designs can be improved by sending them to a toy manufacturing company that will best adapt the circuit and cotton designs for space optimization and reduce overall costs.

Circuitry

PCB board designs like the ones below will be developed with the latest prototype and then sent to a PCB manufacturing company to reduce size, costs, and increase efficiency.





Figures 11, 12: PCB designs - Made on EasyEDA

The PCB’s compact design will also help safety considerations as well as utilizing heat conductivity and dissipation principles/materials.

Improving Microcontroller Capabilities

To make the toy more effective and versatile upcoming versions should concentrate on enhancing the microcontroller features. This may include:

Upgraded Data Processing: Making sure that the microcontroller can manage amounts of data and process it instantly.

Energy Management

Energy Conservation: Creating even better energy algorithms to prolong battery life and ensure that the toy can function for longer durations, without frequent recharging.

Power Consumption

- The toy will include a DC-DC converter to ensure stable voltage levels across the different components, especially when batteries start to deplete.
- Efficiency: A DC-DC converter might have around 80-90% efficiency, meaning some power loss, but not significant enough to heavily impact battery life.
-

Sensor Addition and Improving Sensor Accuracy:

Consider upgrading to higher-quality sensors with better precision and stability. Make a machine learning model to incorporate audio detection. Add the rest of the sensors from Table 5. Add other sensors such as touch, proximity, EDA, pressure sensors or even optional location monitoring for parents. The temperature sensor in MAX30102 can also be used to detect fever (common in cancer patients).

Sensor and Circuit Flexibility

Providing the sensors and circuits as individual items offers versatility in case children doesn't like any of the available models:

- Personalized Integration: Allowing parents or children to incorporate the sensors into their toys by following online guides and tutorials.
- Safety Guarantee: Creating the circuits, with safety measures to avoid choking risks and ensure assembly.

Expand onto other Products

Healpet can expand into other products that can monitor mental and emotional health, and report them through the same app for a more holistic approach and more continuous monitoring. A weighted blanket, for example, could provide additional support while tracking vitals and serving as an anxiety reliever.

Interactivity

Children expressed wanting to interact more personally with HealPet. In the later versions, the toy will be upgraded to have communication features based on the feedback received from children during testing. By adding functions that allow the toy to speak and engage in interactions it can become a more responsive and comforting playmate. This could include using technology that generates speech to let the toy share personalized messages, stories and words of comfort. Furthermore, by incorporating voice recognition and natural language processing (NLP) the toy can verbally respond to what the child says, creating a bond. For instance, the toy might inquire about how the child's day went, offer feedback or suggest calming activities if it senses distress. HealPet can be created to interact with the child in a manner that feels genuine and reassuring. The toy has the ability to softly inquire, "How are you feeling?" giving the child the freedom to reply according to their comfort whether it’s a “yes" or "no," or by embracing the toy. HealPet will utilize JITAI principles to offer timely and relevant comforting messages. These could include:

"Everything will be okay."

"Tomorrow will be a better day."

"Sleep tight."

"Goodnight."

"You are valuable."

"I love you."

The aim is to offer a feeling of companionship and encouragement without overwhelming the child. These improvements in interactivity will not make playing with the toy more exciting which can help foster a deeper emotional connection. This will turn HealPet into a valuable source of support for children going through treatment.

Adaptive Interventions

Activities for Emotional Support

If sensory distractions do not work appropriately, alerts are sent to caregivers and/or parents. However, parents and or caregivers will not always be available shortly to comfort children. In the meantime, HealPet can help children in managing their emotions HealPet by providing a range of activities:

1. Breathing Exercises: HealPet can help children practice breathing techniques coordinating movements or lights with the breathing pattern to promote relaxation.

2. Singing Together: HealPet can sing soothing songs along, with the child fostering a sense of companionship and comfort.

3. Mindfulness Prompts: HealPet encourages children to focus on thoughts or visualize settings to shift their attention from stressors.

4. Comforting Words During Medical Procedures: HealPet can say phrases like "Don't need to be scared to take your medicine" easing anxiety during procedures.

Machine Learning Integration

Incorporating machine learning into HealPet is a future step to customize the device to cater to the unique requirements of children living with long term illnesses such as chronic pain. To provide effectiveness and efficiency, this requires collecting a range of data from a diverse set of children in various situations. My time spent volunteering at Dartmouth Hitchcock Medical Center and Children’s Health at Dartmouth (ChaD) Inpatient Unit has highlighted the significance of distinguishing between times when children are at rest as opposed to engaging in physical activities or experiencing emotional changes. Gathering information from different situations such as the aforementioned scenarios, helps us pick out important characteristics like the average variability of heart rate the way one moves and the trends in oxygen saturation levels.These characteristics are crucial, for comprehending and foreseeings a child's behavioral tendencies enabling HealPet to provide customized and impactful measures. Utilizing learning techniques such as decision trees or support vector machines can help categorize moods. Studies have shown that decision trees are adept at sorting signals into emotional states with great precision [114]. These methods play a role in recognizing emotions, interpreting play habits and forecasting distress levels to suggest appropriate interventions matching the child's emotional requirements, for HealPet.

App Development

Creating the HealPet app involves receiving data using wireless communication methods while prioritizing data privacy and security for HIPAA compliance when transmitting over Bluetooth Low Energy (BLE) or Wi Fi networks. The instant display of real time information on a child's emotions and engagement with the toy offers insights to parents and caregivers, for proactive emotional assistance. Moreover, examining trends in how much time children spend playing and having their actions depicted in visual representations like graphs and charts, parents can improve their insight into their child's well-being. This can allow parents to supervise and assist their children better. Summaries provided on a monthly basis about progress in mental health, behavior, and mood can aid in identifying consistent trends and improvements over an extended period.

Data Exchange and Privacy

Data Exchange must be done by sharing information safely with healthcare providers for patient care. This can be done by allowing therapists to log into the app to oversee the child’s progress and adjust treatment strategies aligning with healthcare regulations (HIPAA) and with protected Access (login credentials for accessing records). This way HealPet not only helps the child at home but also fits in with wider healthcare requirements by becoming a seamless part of the child's complete treatment plan.

User Experience and Personalization

HealPets user interface can aim for an interactive experience tailored for both children and parents alike through separate apps designed for each group's specific requirements. The children's app can prioritize emotional comfort and cognitive growth by drawing inspiration from popular apps, like Sago Mini, which can significantly develop children's emotional resilience [115]. The app for parents can offer in depth monitoring of development to help them track and assist their child's growth as time goes by.

To make the user experience better the app will have a layout that's easy to use, it will support various languages and where parents and children can customize panels for a more personal touch. Interactive guides will help them set up and navigate the app easily while user profiles let parents track each child's behaviors and moods. The smart learning algorithms will adapt to how each child responds, giving them a custom experience that evolves as they grow.

Enhancements and Compatibility/Accessibility

Furthermore, consistent updates and input from users will fuel the enhancement of the application to keep it current and efficient. By developing the application to work on platforms and devices and integrating accessibility functions like voice commands and screen readers HealPet can cater to a diverse user base including individuals with disabilities.

Cognitive Development

HealPet can go beyond recognizing and responding to emotional needs; it can also play a role in fostering overall childhood development by offering educational features tailored to children of different ages and developmental levels The platform can serve as a tool for cognitive development by including activities like matching games for younger children and challenging puzzles or educational tasks for older children. Research indicates that providing such age-appropriate educational content can greatly boost children's cognitive skills when personalized to their specific stage of development [116]. HealPet can then serve as more than a source of emotional comfort; it can also function as a holistic platform for nurturing childhood growth and development.

Potential Partnerships

Partnerships, with Medical Facilities, Therapists and Healthcare Institutions

To support wider dissemination of the device, I next aim to partner with care facilities, therapists and healthcare institutions to validate and incorporate the toy into various care environments. This would ensure that it effectively promotes children's well-being and adheres to standards. By collaborating with these professionals, we could enhance the toy's capabilities and demonstrate its value in hospital settings which would help broaden its utilization as an additional resource.

This can be accomplished through:

- Pilot Programs: Initiating pilot programs in facilities, therapy centers and hospitals to evaluate the toys performance and its impact on children's physical health. These trials will yield insights into the toy's effectiveness. Identify areas for enhancement.
- Training: Conduct training sessions for therapists, medical staff and hospital personnel to acquaint them with the toy's functionalities as a monitoring and intervention tool. Offer resources like brochures and demonstration sessions to support healthcare providers well as families in understanding the benefits of using the toy.

- Feedback: Gather feedback from staff members, patients and families throughout and after the pilot programs. Utilize this feedback to enhance the toys features based on user needs while addressing any arising concerns effectively.
- Recommendations and Marketing: Get recommendations, from facilities and healthcare experts to establish trust and reliability in the toy's efficacy. Use these endorsements to highlight the advantages of the toy and incorporate it into therapy programs for children.

Collaborating with Toy Companies

I am also excited about the possibility of partnering with toy companies like Build A Bear, Barbie (Mattel), American Girl, and Hasbro to allow for more personalization. Potential directions involve integrating the toy into existing product lines or creating versions that incorporate branded elements reflecting each company's style and values. By doing so, we could also make use of the reaching distribution networks and marketing expertise of these companies to expand the toys reach, thereby increasing its presence in the market and making it more accessible.

This can be accomplished through:

- Collaborative Design Projects: Work together with toy companies to develop customized editions of the toy. For example, Build A Bear could offer personalized stuffed animals with features integrated, enabling children to tailor their toys according to their preferences and requirements.
- Special Edition Launches: Create limited edition versions of the toy featuring designs inspired by brands, like American Girl and Barbie including accessories related to care hospital scenarios or supportive tools.

- Collaborative Marketing Initiatives: Initiate marketing efforts, with toy companies to showcase the toy through various channels such as online platforms, retail outlets and events. These campaigns will spotlight the features and advantages of the toy engaging customers and spreading awareness across diverse market segments.

12.4 Quantitative Testing

12.4.1 Hospital Testing

Having established the accuracy of the sensors in a general population, an important next step is to obtain IRB approval to test toy prototypes on pediatric populations at the hospital over longitudinal studies to evaluate the toy's ability to monitor a patient's health and recovery status. Another interesting future direction could be to compare HealPet's biometric data with those from hospital-approved sensors.

12.4.2 EEGs

EEGS will be done to further validate the veracity of the results as performed by the HealPet by scanning the neuronal waves of children and to explore how such passive measures align with their actual feelings.

12.5 Cost Analysis

The final cost of HeaPet comes to about $57 dollars including features that the prototype didn't have such as touch, EDA and pressure sensors, packaging, and domestic shipping. This cost goes down to approximately $43.1 with large scale manufacturing.

Cost can be reduced by bulk manufacturing, established PCB boards that can be ordered from China, and partnering with companies, reducing labor, packaging and shipping costs. The final retail cost (production+marketing+distribution+retail profit margin) can place the final product cost anywhere between $90 and $110. The cost for HealPet with large scale manufacturing could be somewhere around $70 to $90. These costs can be reduced further by subsidies given through partnerships with healthcare providers, insurance companies, and stakeholders as well as optimizing designs and digital marketing strategies-direct-to-consumer sales. A more detailed analysis of how these costs were roughly estimated can be found in Appendix V.

12.6 Long-Term Contributions:

- Advancements in Medical Engineering: This project contributes to engineering by merging sensors and tangible interfaces to address the well-being of pediatric patients.
- Comprehensive Patient Care: This project promotes a more comprehensive approach to patient care by addressing well-being alongside treatment.
- Innovative Therapeutic Aids: These monitoring companions provide therapists with a tool for more effectively understanding and catering to the needs of young patients.
- Simple yet Effective Innovation: This initiative showcases how solutions can make emotional support more accessible and cost-effective in healthcare settings.
- Laying the Foundation for Future Progress: The project sets the groundwork for advancing, broadening, and bringing to market monitoring companions for a range of therapeutic uses.

12.6.1 Expanding to Other Conditions

Once some of these changes are made, adapting the toy for children with other conditions would be an exciting next step offering many potential alternatives. Some of these include:

- Autism Spectrum Disorder: Developing features tailored to the needs of children with ASD such as sensory stimulation, role playing scenarios, communication support.
- Mental Disabilities: Customizing the toy for children with cerebral palsy, epilepsy, and other mental disabilities by monitoring seizures, providing educational content and sending emergency alerts.
- Diabetes Management: Integrating sensors to monitor glucose levels and provide insulin reminders.

12.7 Safety

Here are the primary safety factors that will be taken into account:

Electrical Safety:

- All electronic parts function at low voltages, such as 3.3V or 5V to decrease the risk of shock.
- Will utilize approved high-quality batteries equipped with circuits to prevent issues like overcharging, short circuits.
- All cables and electronic components will be properly insulated to avoid exposure to elements.

Mechanical and Material Safety:

- All materials utilized in HealPet including the casing, fabrics and internal parts will be non-toxic and hypoallergenic while meeting safety criteria, for childrens toys (ASTM F963, EN 71).
- Will double check that all components are securely attached, avoiding parts that could be a choking hazard.
- Will ensure that all edges and surfaces are smooth, without any edges or rough spots to prevent injuries.
- The toy will be sturdy enough to withstand play and accidental drops without breaking or exposing parts.

Fire Safety:

- Will choose fire resistant materials for the outer shell and inner padding to reduce the risk of fires.
- HealPet will incorporate thermal safety features that can automatically turn off the device if it detects overheating.

Ergonomic and Psychological Safety:

- HealPet has been designed to be comfortable for children to hold and play, ensuring they don't experience any discomfort.
- HealPet will be programmed to respond in a suitable manner based on the child's emotions avoiding anything that might cause distress or worry.

- HealPet's features and content are appropriate for the age group it targets, keeping interactions simple and clear.

Radiation Safety:

- Radiofrequency emissions will be within safety limits as defined by health authorities.
- Will follow safety standards regarding electromagnetic emissions set by organizations such as FCC or CE.

Hygiene and Maintenance:

- Where possible make parts of the toy that contact a child's skin washable to promote hygiene.
- Incorporate coatings or materials to reduce the risk of germ transmission.

Software Safety:

- Incorporate safety measures into the software to ensure that if a malfunction occurs the device either shuts down safely or responds appropriately.
- Keep the software up to date to address any security vulnerabilities or bugs.

Regulatory Compliance:

- Will make sure HealPet meets all safety certifications for toys, such as those provided by the Consumer Product Safety Commission (CPSC) in the U.S. Or the European CE marking.
- Will conduct safety testing, including drop tests, flammability tests and electrical safety tests before introducing the product to market.

13. Conclusions

13.1 Summary of Results

This study has prototyped and tested a toy companion aimed at monitoring and enhancing children's emotional well-being. The toy promotes playtime while also keeping track of distress related to pain and changes in health. The findings indicate that the toy is a resource for children and their families, offering insights into a child's state while engaging them in playful activities that can have therapeutic benefits.

In essence, this research underscores the benefits of combining support tools with physical health monitoring to provide comprehensive care for pediatric patients. The toy's effectiveness in enhancing children’s well-being and potential applications in healthcare is evident.

13.2 Contributions of this Study

This study provides contributions to pediatric care and emotional well-being using innovative technology.

1. Integration of Emotional Support with Physical Health Monitoring:

This research advances our understanding of integrating child-centered emotional support tools with health monitoring by introducing a toy companion that monitors both emotional and physiological data. It showcases the advantages of addressing both physical aspects in pediatric care. This innovative approach bridges the gap between devices and easily accessible child-friendly tools, boosting the involvement and cooperation of young patients.

2. Encouragement of Play and Emotional Well-being:

Apart from being a monitoring tool, the toy friend also encourages play, which is vital for children's mental well-being. Research indicates that play can effectively serve as a technique to enhance mood and emotional condition marking progress in non-invasive emotional support measures.

3. User-Centered Design and Feedback:

By considering input from children and their families the study highlights the significance of user focused design when creating devices for children. This strategy ensures that the devices are not practical but also attractive and user friendly enhancing their efficacy and acceptance.

4. Foundations for Future Technological Enhancements:

The study sets the stage for progress like refining microcontroller functions, developing machine learning algorithms, for data analysis and improving calming features. These upcoming advancements have the potential to further enhance the usefulness and influence of the monitoring companion.

5. Potential for Market Expansion and Wider Adoption:

The research sets the stage for production of these toys making them more accessible as products. This growth could increase the use of the technology positively impacting a number of children dealing with long term illnesses.

Overall, this study adds value to areas like children's healthcare, emotional wellness and medical technology by showcasing a blend of play therapy with health tracking. It also establishes a model for advancements in child-friendly medical tools.

13.3 Final Words

The development of therapeutic toys highlights the importance of play in healing and growth. HealPet combines fun learning and therapy to monitor health indicators and deliver personalized intervention, nurturing strength and progress in people. As technology progresses, the opportunity for personalized therapeutic toys brings hope for enhanced inclusivity.

14 Appendices

14.1 Appendix I: Blender/CAD(.stl)

Models

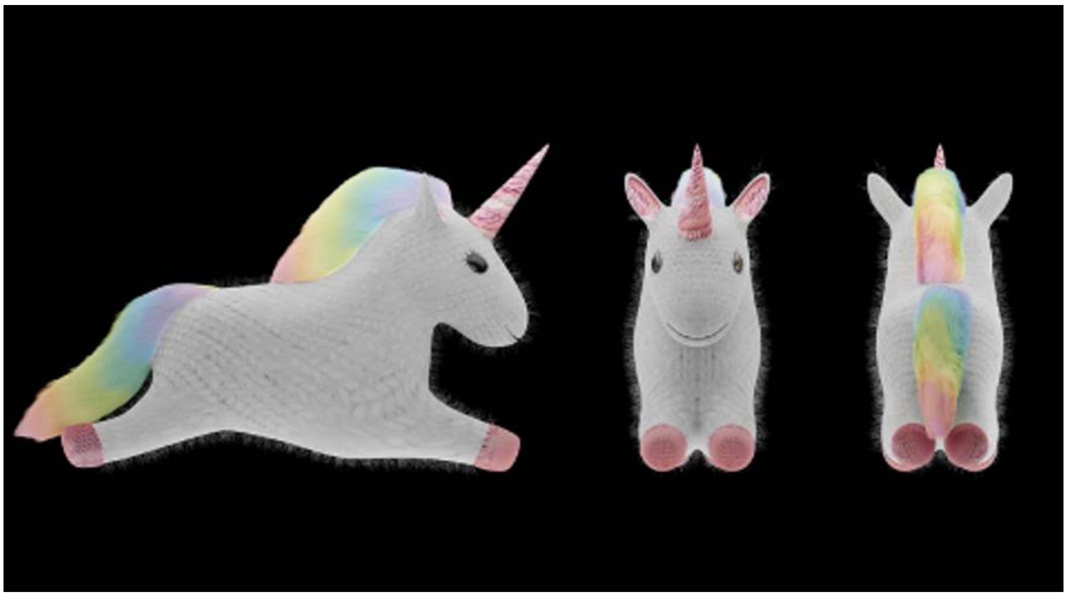


Figure 13: Unicorn Blender Model

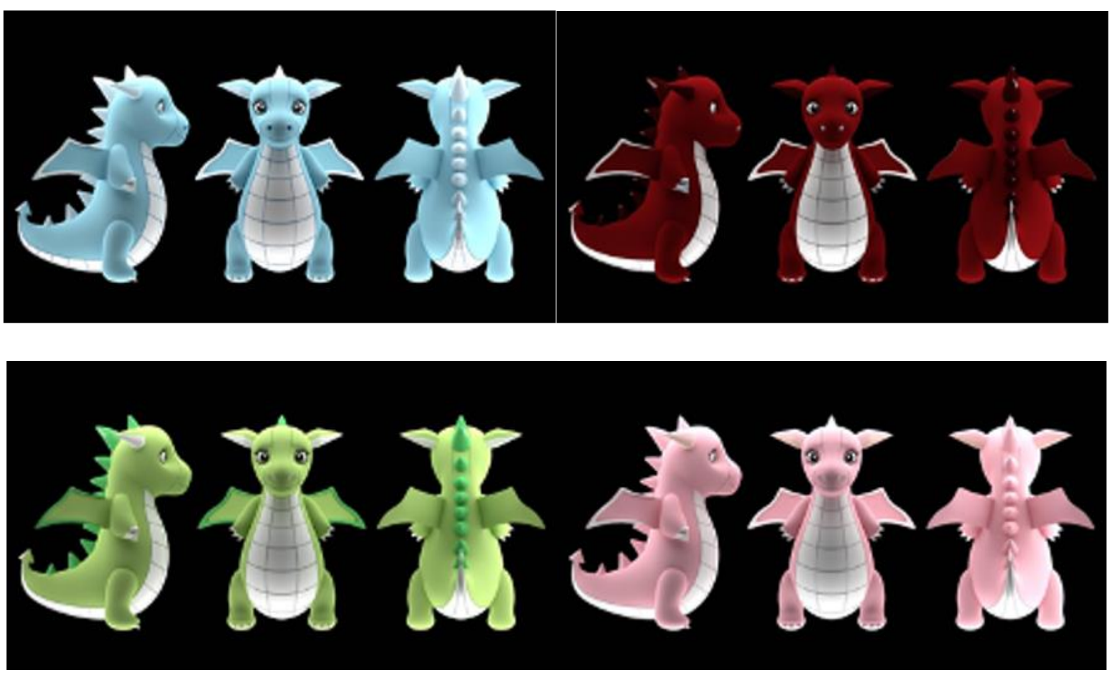


Figure 14,15,16,17: Dragon Blender Models

Figure 18,19,20,21: Penguin Blender Models

14.2 Appendix II: Photos of 3D Printed Models and Prototypes

14.2.1 3D Printed Models

Figure 22: Small TPU unicorn-machine shop

Figure 23: First TPU Unicorn- Maker's Space

Figure 24: First TPU Penguin and Dragon with PLA filaments-Maker's Space

Figures 25,26,27: First PLA prints-Machine Shop

Figures 28,29: More PLA prints

14.2.2 Stuffed Animals for Prototypes

Figures 30,31, 32,33: Stuffed Animals for Tests

14.3 Appendix III: Code

Prototype Code

```
#include <Wire.h>

#include "MAX30105.h"

#include "spo2_algorithm.h"

#include <SoftwareSerial.h>

#include <LiquidCrystal_I2C.h>

LiquidCrystal_I2C lcd(0x27, 16, 2);

const int mp3SerialRx = 10;  // Connect to the TX pin

const int mp3SerialTx = 11;  // Connect to the RX pin

const int judgePin = 1; // for test

const int motorPin1 = 2;  // IN1

const int motorPin2 = 3;  // IN2

const int enablePin = 5;  // ENA (PWM pin)

SoftwareSerial mp3Serial(mp3SerialRx, mp3SerialTx);

MAX30105 particleSensor;

#define MAX_BRIGHTNESS 255

#if defined(__AVR_ATmega328P__) || defined(__AVR_ATmega168__)

uint16_t irBuffer[100];

uint16_t redBuffer[100];

#else

uint32_t irBuffer[100];
```

```
uint32_t redBuffer[100];

#endif

int32_t bufferLength;

int32_t spo2;

int8_t validSPO2;

int32_t heartRate;

int8_t validHeartRate;

byte pulseLED = 11;

byte readLED = 13;

const int xpin = A1;

const int ypin = A2;

const int zpin = A3;

float threshold = 6;

float xavg, yavg, zavg;

int steps, flag = 0;

void setup()

{

  Serial.begin(115200);

  mp3Serial.begin(9600);

  Wire.begin();

  pinMode(pulseLED, OUTPUT);

  pinMode(readLED, OUTPUT);

  pinMode(motorPin1, OUTPUT);

  pinMode(motorPin2, OUTPUT);
```

```
  pinMode(enablePin, OUTPUT);
  pinMode(judgePin, INPUT);
  lcd.begin(16, 2);
  lcd.backlight();
  lcd.clear();
  Serial.println(F("Attach sensor to finger with rubber band. Press any key to
start conversion"));
  Serial.read();
  stopMotor();
  byte ledBrightness = 60;
  byte sampleAverage = 4;
  byte ledMode = 2;
  byte sampleRate = 100;
  int pulseWidth = 411;
  int adcRange = 4096;
  sendCommand("AT+MP3INIT");
  calibrate();
}
void loop()
{
  bufferLength = 100;
  for (byte i = 0; i < bufferLength; i++)
{
      while (particleSensor.available() == false)
      particleSensor.check();
```

```
redBuffer[i] = particleSensor.getRed();
        irBuffer[i] = particleSensor.getIR();
        particleSensor.nextSample();
        Serial.print(F("red="));
        Serial.print(redBuffer[i], DEC);
        Serial.print(F(", ir="));
        Serial.println(irBuffer[i], DEC);
  }
  maxim_heart_rate_and_oxygen_saturation(irBuffer, bufferLength, redBuffer,
&spo2, &validSPO2, &heartRate, &validHeartRate);
  // Step counting
  for (int w = 0; w < 16; w++) {
        lcd.write(byte(0));
        delay(500);
  }
  int acc = 0;
  float totvect[100] = {0};
  float totave[100] = {0};
  float xaccl[100] = {0};
  float yaccl[100] = {0};
  float zaccl[100] = {0};
  for (int a = 0; a < 100; a++)
{
        xaccl[a] = float(analogRead(xpin) - 345);
        delay(1);
```

```
yaccl[a] = float(analogRead(ypin) - 346);
    delay(1);
    zaccl[a] = float(analogRead(zpin) - 416);
    delay(1);
    totvect[a] = sqrt(((xaccl[a] - xavg) * (xaccl[a] - xavg)) + ((yaccl[a] -
yavg) * (yaccl[a] - yavg)) + ((zaccl[a] - zavg) * (zaccl[a] - zavg)));
    totave[a] = (totvect[a] + totvect[a - 1]) / 2;
    Serial.println("totave[a]");
    Serial.println(totave[a]);
    delay(100);
    if (totave[a] > threshold && flag == 0)
    {
    steps = steps + 1;
    flag = 1;
    }
    else if (totave[a] > threshold && flag == 1)
    {
    // Don't Count
    }
    if (totave[a] < threshold && flag == 1)
    {
    flag = 0;
}
    if (steps < 0) {
    steps = 0;
```

```
}
        Serial.println('\n');
        Serial.print("steps: ");
        Serial.println(steps);
        lcd.print("Steps: ");
        lcd.print(steps);
        delay(1000);
        lcd.clear();
 }
}
void MPU6050_Init()
{
  Wire.beginTransmission(MPU6050_ADDRESS);
  Wire.write(0x6B);
  Wire.write(0);
  Wire.endTransmission(true);
}
void readAccelerometerData(int16_t &AcX, int16_t &AcY, int16_t &AcZ)
{
  Wire.beginTransmission(MPU6050_ADDRESS);
  Wire.write(0x3B);
  Wire.endTransmission(false);
  Wire.requestFrom(MPU6050_ADDRESS, 6, true);
  AcX = Wire.read() << 8 | Wire.read();
  AcY = Wire.read() << 8 | Wire.read();
```

```
AcZ = Wire.read() << 8 | Wire.read();

}

void sendCommand(String command)

{

mp3Serial.println(command);

delay(100);

while (mp3Serial.available())

{

        Serial.write(mp3Serial.read());
```

Voice Recognition Code

```
#include <SoftwareSerial.h>

#include "VoiceRecognitionV3.h"

// Arduino RX pin 10

// Arduino TX pin 11

SoftwareSerial mySerial(10, 11);

VR myVR(mySerial);

uint8_t records[7];

uint8_t buf[64];

int ledPin = 13;

void setup() {

mySerial.begin(9600);

Serial.begin(9600);

pinMode(ledPin, OUTPUT);
```

```
 if (myVR.begin()) {
    Serial.println("Ready to receive voice commands.");
  } else {
    Serial.println("VR not detected!");
  }
}
void loop() {
  int ret = myVR.recognize(buf, 50);
  if (ret > 0) {
    switch (buf[1]) {
      case 0:
        Serial.println("Command 0 recognized.");
        digitalWrite(ledPin, HIGH);
        break;
      case 1:
        Serial.println("Command 1 recognized.");
        digitalWrite(ledPin, LOW);
        break;
      default:
        Serial.println("Command not recognized.");
    }
   }
}
// "Elechouse Voice Recognition Module"
```

Bluetooth Code

```
#include "BluetoothSerial.h"
#if !defined(CONFIG_BT_ENABLED) ||
!defined(CONFIG_BLUEDROID_ENABLED)
#error Bluetooth is not enabled! Please run `make menuconfig` to enable it
#endif

BluetoothSerial ESP32_BT; // Object for Bluetooth
void setup() {
  Serial.begin(115200);
  ESP32_BT.begin("ESP32test");
  Serial.println("Bluetooth device is ready to pair");
}
void loop() {
  if (ESP32_BT.available()) {
    String data = ESP32_BT.readString();
    Serial.print("Received data via Bluetooth: ");
    Serial.println(data);
    ESP32_BT.println("Echo: " + data);
  }
  delay(20);
}
// data
```

14.4 Appendix IV: User studies/interview questions and answers

14.4.1 Pre-Testing

Survey Questions for child life specialists and psychologists:

1. Which psychological signs should the toy keep track of to offer insights?
2. How can therapists and families make the best use of the data gathered by the toy?
3. What kinds of interactions or activities would be most helpful in fostering emotional well-being through play?
4. How crucial is it for the toy to offer immediate feedback or interventions based on the child's actions and mood?
5. What are the factors that would guarantee that children of ages and abilities find it easy to use the toy?
6. How do we ensure that the toy continues to captivate over time?
7. In what ways can we incorporate the toy into methods and everyday routines?
8. What are effective methods to train families and caregivers in using the toy proficiently?
9. What are the best ways to gather feedback from children, families and healthcare providers about the toy?
10. How do we make sure that the feedback leads to improvements in the toys design and features?
11. How can we assess the lasting effects of the toy on a child's emotional and mental well-being?
12. Which results should we focus on when evaluating how effective the toy is?

13. What safety issues should we consider when creating a toy for children with weakened systems or other health vulnerabilities?
14. How can we make sure that the toy is physically comfortable and gentle for children who're in pain?
15. How crucial is it to provide customization choices in designing and functions of the toy to meet preferences and needs?
16. Which aspects of the toy can be personalized to improve its effectiveness and appeal?

14.4.2 Testing

Survey Questions for children:

1. How much did you enjoy playing with the smart toy during the session? (Scale: Not Fun at All to Extremely Fun)
2. Was it easy for you to use the smart toy? Why or why not?
3. What was your favorite thing about the smart toy?
4. Understanding the Toy:
5. Can you tell us what the smart toy does in your own words?
6. Were there any parts of playing with the smart toy that you found confusing or difficult?
7. Do you think the smart toy understands how you feel? Why or why not?
8. Usability and Likability:
9. On a scale from 1 to 10, how easy was it for you to use the smart toy? (1 being very difficult, 10 being very easy)
10. On a scale from 1 to 10 how much did the music and lights help you feel better?

11. Which features of the smart toy did you like the most, and which ones could be improved?
12. Would you want to play with this smart toy again? Why or why not?

It is okay to skip some of these if the children are too young

Survey Questions for Parents:

1. How would you rate your child's overall experience during the play session with the smart toy? (Scale: Negative to Positive)
2. Did you observe your child's challenges or positive reactions during the session?

14.5 Appendix V

Cost Justification

Table 16: Costs Analyses

Item	Prototype	Manu (100-500)	Red. Manu. (1k-5k)	Manu+Sensors	Red. Manu.+Sensors
Arduino Nano [117]	24	10	8	10	8
ESP-WROOM-32 ESP32) [118]	15	5	4	5	4
MAX 30102 [119]	10	3	2.5	3	2.5
Accelerometer [120]	5	1.5	1.2	1.5	1.2
Voice Recognition [121]	12	4	3.5	4	3.5
Vibration Motor [122]	3	1	0.8	1	0.8
LED lights [123]	2	0.5	0.4	0.5	0.4
Rechargeable Power	15	6	5	6	5

Supply (4AA Battery Pack) [124]					
Plush materials [125]	20	5	4	5	4
MP3 Player Module [126]	8	2	1.5	2	1.5
EDA [127]	0	0	0	2	1.5
Touch Sensor [128]	0	0	0	0.5	0.4
Pressure [129]	0	0	0	1	0.8
Speakers [130]	5	1	0.8	1	0.8
Misc. (wires, connectors, etc.) [131]	5	1	0.8	1	0.8
Manufacturing Labor [132]	0	2	1.5	2	1.5
Packaging [133]	0	0.5	0.4	0.5	0.4
Shipping [134]	0	1	0.8	1	0.8
Total (Materials +Manufacturing)	120	43.5	36.4	53	46.4
Manufacturing Costs	0	5	4	5	4
Company Gains (20%) [135]	0	9.7	8.1	11.6	10.1
Total with Company Gains	0	58.2	48.5	69.6	60.5

The percentage reductions listed in the table above for large scale manufacturing were determined based on industry standards and the typical impact of economies of scale than specific data related to HealPet. These values were generally established through:

Cost Reductions: In manufacturing sectors cost reductions ranging from 10% to 30% are often observed when transitioning from low volume to high volume production due to factors like economies of scale, bulk buying and operational efficiencies. For instance, electronic components such as microcontrollers typically experience price drops of 20% to 25% with purchases. Within electronics production it's typical to witness material cost reductions between 15% and 30% when shifting from scale to large scale operations varying based on the component and supplier [135,136,137].

The decrease from \$10 to \$8, per unit (a 20% reduction) is attributed to volume discounts that suppliers like DigiKey or Mouser may offer for orders compared to quantities. The price of sensors, like the MAX30102 has been lowered from \$3 to \$2.5 per unit showing a 16.7% decrease, which's common when buying in quantities of 1,000 or more. Reductions in labor costs for example from \$2 to \$1.5 (a 25% decrease) are projected based on improved efficiency. Streamlining production processes in a high-volume environment [138].

Fixed expenses (such as design, setup and tooling) are spread out over units resulting in per unit costs. This typically leads to cost savings as production scales up. Variable expenses like labor and materials can cause a substantial decrease in the overall reduction in cost per unit when these savings are combined [139,140].

Assumptions for HealPet:

In the case of the HealPet project these percentage reductions were selected based on industry standards for consumer electronics and toy manufacturing sectors. The specific percentages used (e.g. a 20% reduction for microcontrollers or a 16.7% reduction for sensors) are assumptions aligned with industry norms rather than precise data, from the HealPet production process [141].

Using the percentage reduction formula, across elements in the chart to project cost changes as production scales up. This approach gives an estimate of potential cost savings [142].

Microcontroller (from $10 to $8);

Percentage Decrease = 20%

Labor Cost (from $2 to $1.5);

Percentage Decrease 25%

The specific percentage reduction figures in the table were determined by considering industry standards, typical cost reduction patterns for parts and general assumptions about how costs decline with higher production volumes. These figures serve as estimates based on practices in similar industries offering a practical guide for planning and financial projections, within HealPets large scale manufacturing context [143].

14.6 Appendix VI

Safety

Electrical Safety [144, 145]

- Operates at low voltages (3.3V or 5V) to minimize shock risk
- Uses high-quality batteries with safety circuits
- All components and cables are well-insulated

Mechanical & Material Safety [146, 147]

- Non-toxic, hypoallergenic materials meeting ASTM F963, EN 71 standards
- Securely attached components to prevent choking hazards
- Smooth edges; durable to withstand play and drops

Fire Safety [148, 149]

- Fire-resistant materials for casing and padding
- Thermal safety features to prevent overheating

Ergonomic & Psychological Safety [150, 151]

- Designed for comfort, avoiding discomfort during play
- Appropriate emotional responses; age-appropriate content

Radiation Safety [152]

- Radiofrequency emissions within safe limits (FCC, CE standards)

Hygiene & Maintenance [151]

- Washable parts; materials reduce germ transmission

Software Safety [150, 153]

- Safe shutdowns or appropriate responses in case of malfunctions
- Regular software updates to fix vulnerabilities

Regulatory Compliance [154]

- Meets CPSC, CE, and other relevant safety certifications
- Undergoes comprehensive safety testing before market release

14.7 Appendix VII

Material Analysis

Here's an evaluation of the materials based on key factors such as hypoallergenic properties, softness, cost, durability, and suitability for HealPet:

1. Organic Cotton [155,156]

- Hypoallergenic and breathable
- Very soft and comfortable
- Moderately priced, but can be more expensive than synthetics. Costs can be managed by buying in bulk.
- Good durability , but it may wear out faster with frequent washing and use compared to synthetic options.

Suitability for HealPet: Ideal for direct skin contact areas due to its hypoallergenic nature and softness. Suitable for exterior coverings.

2. Bamboo Fabric [157,158]

- Hypoallergenic and antimicrobial.
- Extremely soft, similar to a silky texture
- Generally affordable, although prices can vary depending on quality.

- Good durability, maintains softness and structure over time, though it can be prone to pilling.

Suitability for HealPet: Excellent choice for areas that will have direct skin contact. Its natural properties are beneficial for children with sensitive skin.

3. Polyester Fleece [159,160]

- Can be treated to be hypoallergenic, though some sensitive individuals may react to synthetic fibers.
- Extremely soft and plush.
- Very affordable and widely available.
- Highly durable, resists shrinking and wrinkles. Can last through many washes.

Suitability for HealPet: Suitable for the exterior of the toy, providing a soft, comforting feel. May not be ideal for very sensitive skin due to its synthetic nature.

4. Microfiber [161,162]

- Hypoallergenic
- Very soft, smooth texture.
- Affordable and cost-effective, especially when purchased in bulk.
- Very durable, resistant to stains and fading. Can be washed frequently without significant wear.

Suitability for HealPet: Good for both exterior and interior components. It provides a soft feel and is safe for children with allergies.

5. Lyocell (Tencel) [163,164]

- Naturally hypoallergenic and resistant to dust mites.
- Very soft, often compared to silk or cotton.
- More expensive than polyester and cotton but affordable compared to luxury fabrics.
- Durable, with excellent moisture-wicking properties. Maintains softness over time.

Suitability for HealPet: Ideal for skin-contact areas due to its hypoallergenic properties and comfort. Suitable for both interior and exterior.

6. Minky Fabric [165,166]

- Hypoallergenic
- Extremely soft and plush, with a velvety texture.
- Moderately priced, depending on the quality and texture
- Good durability, but it can show wear and tear with repeated washing

Suitability for HealPet: Excellent for creating a comforting, plush exterior. However, it's synthetic, so it may not be ideal for all children with skin sensitivities

7. Silicone [167,168]

- Hypoallergenic, non-reactive and safe for sensitive skin (medical-grade)
- Not traditionally "soft," but it is smooth and flexible.
- Higher cost, especially for medical-grade silicone.
- Extremely durable, resistant to heat, water, and physical damage

Suitability for HealPet: Best suited for specific parts of the toy that require flexibility and durability (e.g., buttons, sensory elements). Not ideal for the entire exterior due to its texture.

Table 17: Materials Rating

Rating	Material	Hypo-allergenic	Softness	Cost/yd	Durability	Healpet Suitability	Overall Score
3	Microfiber	Yes	4	5 (~ $5)	5	5	4.75
2	Polyester Fleece	Treated	4	5 (~$4)	5	4	4.5
4	Lyocell (Tencel)	Yes	5	4 (~$7)	4	5	4.5
0	Organic Cotton	Yes	5	3 (~$8)	4	5	4.25
1	Bamboo Fabric	Yes	5	3 (~$7)	4	5	4.25
5	Minky Fabric	Yes	5	4 (~$6)	3	4	4
6	Silicone	Yes (medical-grade)	3	2 (~$15)	5	3	3.25

Overall Recommendations for HealPet:

- Exterior Fabric: Organic cotton or bamboo fabric are top choices for the exterior where skin contact is frequent. Minky fabric can be considered for a plush, comforting feel but should be tested for sensitivity.
- Interior Components: Microfiber and polyester fleece are good for stuffing or padding due to their durability and softness.
- Special Components: Silicone can be used for parts requiring flexibility and durability, like interactive buttons or sensory elements.

14.8 Appendix VIII HiLetgo Technical Features

Here is an overview of its technical features and applications within such toys:

Table 18: HiLetgo Technical Features

Feature	Description
Audio Playback Capability	Supports MP3 format playback, allowing the smart toy to deliver various audio content such as music, instructions, affirmations, and meditations.
UART Interface	Facilitates seamless communication between the module and the controlling microcontroller or processing unit, enabling dynamic control over playback, volume, and track selection.
MP3 Playback	Supports playback of MP3 audio files from an external microSD card, providing a wide range of audio content for mental well-being, including meditation, music, affirmations, etc.
Compact Size	Small form factor allows easy integration into the compact design of smart toys without compromising aesthetics or functionality.
Low Power Consumption	Designed for minimal power consumption, making it suitable for battery-powered smart toys intended for continuous mental health monitoring.

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