THE DIAGNOSTIC PACIFIER

BIOMEDICAL ENGINEERING
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EXECUTIVE SUMMARY

Far too often, predictive factors for disease go unnoticed in developing children, which can lead to debilitating and long lasting effects. These adverse effects impact the cost of health care later life but more importantly could have a negative effect on their quality of life. We have the ability, at this critical life stage, to implement an easy to use at home monitoring system that healthcare providers could use to identify disease risk factors in their patients and prescribe early treatments. This form of proactive intervention can not only drastically reduce the cost and complexity of treatment but also more importantly increase the effectiveness.

PROBLEM AND CLINICAL NEED

CLINICAL PROBLEM

Symptoms of cognitive impairment detected early in a child's development are most likely indicative signs of intellectual disability

RISK FACTORS GO UNNOTICED → DELAY IN TREATMENT → LOWERED QUALITY OF LIFE

PROBLEM STATEMENT

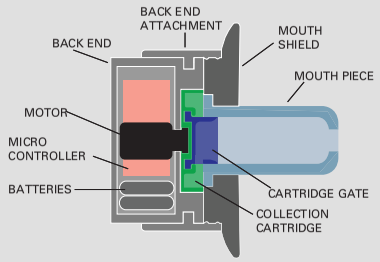
Predictive risk factors go unnoticed or undervalued and delay the onset of treatment, resulting in a lowered quality of life.

MARKET

With our product intended for infants below the age of 24 months, the person purchasing our diagnostic pacifier would be a concerned caregiver. We also expect referrals from pediatricians who are concerned about delays in their patient's motor, learning, cognitive, social, or emotional development. About 9.2 million children in the United States ages 3-17 have developmental disabilities including intellectual disability, cerebral palsy, autism, seizures, stuttering or stammering, hearing loss, blindness, and other learning disorders (1). 8.3 million children ages 4-17 have parents who have talked to a health professional about emotional or behavioral difficulties (2). Considering that children with developmental disabilities often present with a comorbid mood disorder, the potential market can be estimated to be somewhat less than the sum of these two populations.

NOVELTY OF THE DESIGN

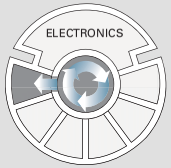
The proposed product is a novel integration of a saliva collection system within a pacifier device. Current saliva methods are often cumbersome and unsuitable or uncomfortable for infants. Many existing collection techniques require the patient to chew on or hold a sponge in their mouth to absorb saliva, which is then extracted from the sponge. This is unsuitable for infants due to the risk of ingestion and choking. Some of these methods have also been shown to reduce the levels of biomarkers present in collected saliva over a passive "drooling" technique. This method requires patients to passively drool into a test tube, but infants are incapable of performing this action for themselves. Our device draws upon the analytically beneficial technique of passive drooling and collects saliva without any inconvenience or discomfort to infant or caregiver. In a search for prior art, many devices integrate a medical functionality into a pacifier device. These functionalities cover a broad spectrum of use, including dispensing medication, monitoring feeding, and measuring body temperature. No device, however, combines the pacifier device with saliva collection. We would anticipate our future competition to be other pacifier devices or infant toys that would incorporate a different method of saliva collection.



The purpose of this design is to enable doctors and parents to noninvasively collect biomarkers for early detection of cognitive impairment. To accomplish this our design employs saliva as the biological sample because it allows for the detection of melatonin and cortisol. We have determined the system for our design will consist of four components. These components will work together to periodically collect saliva samples with little user input, which can then be processed by the doctors who have prescribed this device.

PROTOTYPE & IDEAL MODEL

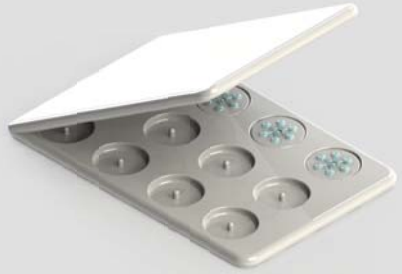
FLOW OF SALIVIA THROUGH CARTRIDGE



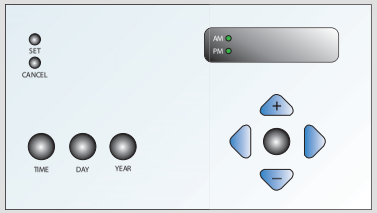
CARTRIDGE WITHOUT SEAL TO SHOW CAPSULE AND GATE

IDEAL MODEL FOR THE PACIFIER

IDEAL MODEL OF CARTRIDGE CASE

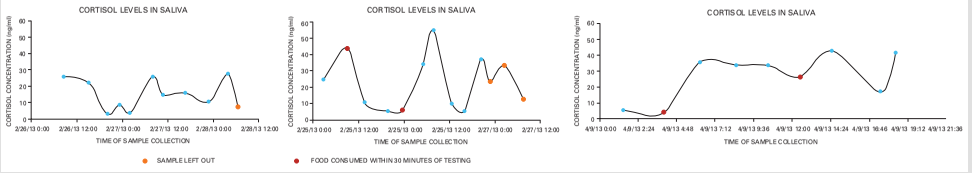


CARTRIDGE CASE BUTTON/DISPLAY LAYOUT



TESTING

This test executed was the cartridge saliva retention testing. This test was to ensure that the capsules within the cartridge were able to retain saliva and did not leak or contaminate the samples. Because the cartridge prototype was 3D printed in three parts, initially the capsules were not sealed and liquid would flow between them. After sealing with additional epoxy, the cartridge was tested and passed the saliva retention test and different colored waters remained in their designated capsule.



RESULTS

Cortisol Levels in Saliva found using ELISA The cortisol concentration was found in saliva collected at six time points each day with the exception of the cortisol concentrations shown in the bottom graph where saliva was collected at twice the frequency. The top and middle graphs show cortisol levels for three consecutive days and the bottom graph shows cortisol levels for one day. The data points highlighted in orange represent samples that were left out and the data points highlighted in red represent samples collected within 30 minutes of consuming food or drink. There was no statistically significant differences found between control samples and those that were left out or may have had interference from food and drink. More data is needed to conclude that these variables do not affect the analysis.

COST

COMPONENT	DETAILS	PRICE	QUANTITY	TOTAL
Nipple	Silicone	$0.04 using ABS plastic injection molding as a facsimile	1	$0.04 using injection molding and ABS plastic as a material.
Mouth shield	ABS	~$0.75/unit	1	$0.75
Cartridge	ABS	~$1.50/unit	1	$1.50
Seal	Aluminum foil	<$0.01/unit	3cm x 3cm	$0.01
EEPROM	Microchip brand 22LC256	$0.65 / per cartridge	1	$0.65
printed circuit board		~$7.00/unit	1	$7.00
Buttons	TSL12121	~$0.25/unit	8	$2.00
7-segment display		~$1.00/unit	1	$1.00
ATMega 328 TQFP	surface mount microprocesso	~$1.50/unit	2	$3.00
mixed surface mount components	voltage regulator, crystal oscillator, resistors, etc	~$3.00/unit	1	$3.00
mini push buttons		~$0.01/unit	2	$0.02
			TOTAL	~$31.56+

REGULATORY PATHWAY

Our device would be considered Class II device by the FDA and would require the submission of an FDA 510(k). This means that our device is similar to already approved products, and we expect that our product would be deemed similar to existing saliva collection systems and electronic pacifier devices already being marketed. We would need to prove that our device is safe, effective and similar to current devices in materials, design, technology, intended use, and performance. For example, in 2008 the FDA approved a 510(k) application for a pacifier device for pre-term infants that combined an existing device to encourage non-nutritive sucking in these infants with a biofeedback software system [cite]. Similarly, our device combines a saliva collection method with an electronic pacifier. Other pacifier devices, such as digital pacifier thermometers, have also completed the 510(k) approval process.

ACKNOWLEDGMENTS

Dr. Conrad Zapanta
Ying Ying Wu
Dr. Robert S Alvin, MD

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