Intertek

Technical Report

Revised Mimos Pillow Carbon Dioxide Rebreathing Assessment

Intertek Report Number WOUK05200

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19 January 2015

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1 INTRODUCTION

1.1 Human Factors Analysis

Human factors analysis is the study of the physical interaction of a consumer and a product. When this interaction is understood, the hazard types and severity levels associated with a product can be determined. The etiology of injuries from consumer products includes three components[1]. These components are exposure to the hazardous characteristics, consequences of contact with the hazard, and mitigation of the effects of the hazard.

1.1.1 Exposure to Hazard

If a consumer can gain access or become exposed to hazardous product characteristics, the probability of this event must be determined. For example, if a small part releases from product. Probable exposure to the hazard may be determined using anthropometrics data, pediatric biomechanics, and foreseeable use analysis. Anthropometrics data and pediatric biomechanics are used to evaluate the impact of size, strength, and kinetic behaviors/capabilities of consumers on their ability to access hazardous product characteristics.

1.1.2 Consequences of Hazard

If a consumer is exposed to hazardous product characteristics, the severity level or potential consequence of this exposure must be evaluated. For example, a small part is aspirated. Human factors analysis is conducted to determine the consequences, or potential product related injuries, based on the foreseeable behaviors consumers will use when interacting with products. Virtual and physical models of the human anatomy are used to effectively diagnose and demonstrate hazardous product characteristics.

Human factors analysis utilizes accurate virtual and physical simulations of the human anatomy to identify the potential hazards posed by consumer products. The conclusions of these analyses are developed with the assistance of, and confirmed by, leading physicians. In order to determine the level of product related hazard, both product characteristics and anatomical characteristics of likely consumers are examined. Virtual and physical human factors tools are used to conduct this research.

1.1.3 Mitigation of Hazard

The severity level of a hazard may be reduced by design characteristics that lead to reduced consequence or decreased time to effective treatment. For example, air passages in a small part may prevent fatal injury.

1.2 Scope of Study

Mimos has requested for Intertek to evaluate the revised MimosPillow for its potential to pose carbon dioxide rebreathing hazards. The evaluation was conducted based on the samples provided by Mimos, as shown in Figure 1 below. The assessment was carried out at room temperature, 23 degrees C.

[1] Haddon, W. J. (1999). The changing approach to the epidemiology, prevention and amelioration of trauma: The transition to approaches etiologically rather than descriptively based. *Injury prevention; 5*; 231-236.

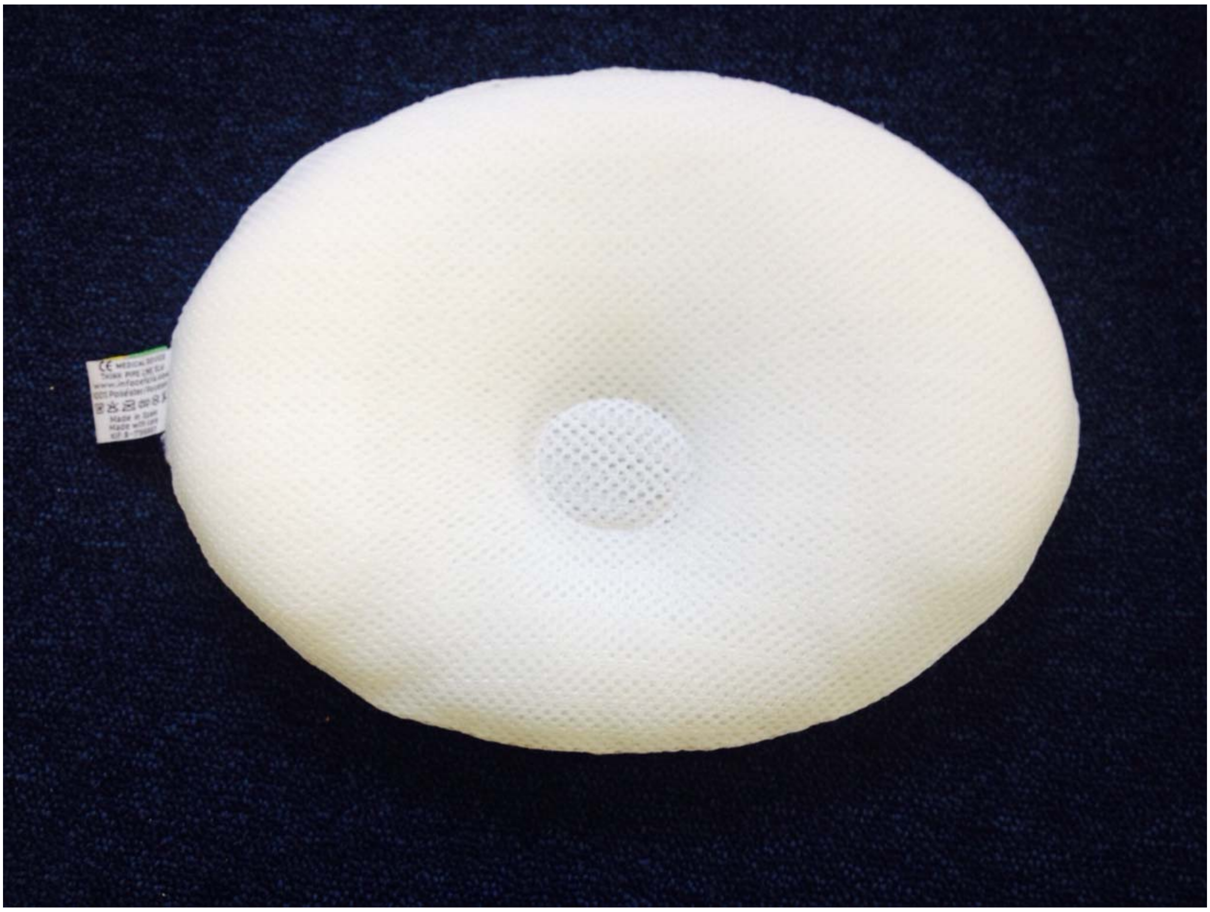

Figure 1 Revised Mimos Pillow Sample

2 CARBON DIOXIDE REBREATHING HAZARD ASSESSMENT

2.1 Carbon Dioxide and the Respiratory System

Carbon dioxide rebreathing increases respiratory effort. Rebreathing of exhaled air is one proposed mechanism for the increased risk for Sudden Infant Death Syndrome (SIDS) among prone sleeping infants.[2] An increased risk for SIDS has been noted for infants at the age of 13 to 24 weeks.[3]

Carbon dioxide (CO_2) is an end product in organisms that obtain energy from breaking down sugars or fats with oxygen as part of their metabolism, in a process known as cellular respiration. This includes all animals, many fungi and some bacteria. In higher animals, the carbon dioxide travels in the blood from the body's tissues to the lungs where it is exhaled. In plants using photosynthesis, carbon dioxide is absorbed from the atmosphere.

The primary function of the respiratory system is to obtain oxygen for use by body's cells and eliminate carbon dioxide that cells produce. The structure includes respiratory airways leading into and out of the lungs as well as the lungs themselves.

2.2 Experiment Design

The capability of the sample provided by Mimos to act as a carbon dioxide reservoir was compared with the capability of products with known levels of hazard. Sheepskins and fabric covered polystyrene bean filled cushions have been implicated in a significant number of SIDS fatalities, and therefore have been selected to represent products with a high level of hazard.[4,5] A firm mattress covered by a cotton sheet has been selected to represent a low level of hazard consistent with the policy statement of the American Academy of Pediatrics task force on SIDS.[6]

The presence of carbon dioxide was evaluated in an area at close proximity to the oral and nasal openings but within the product itself to determine the potential of the product to act as a reservoir for carbon dioxide.

A mannequin representing a one month old infant was used as the interface to evaluate the product. The mannequin was placed with its oral opening against the sample. This position is implicated in SIDS incidents.[7]

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[2] Kemp JS, Kowalski RM, Burch PM, Graham MA, Thach BT Unintentional suffocation by rebreathing: a death scene and physiological investigation of a possible cause of sudden infant death. J Pediatrics 1993; 122:874-880

[3] Oyen, N. et al. Combined Effects of Sleeping Position and Prenatal Risk Factors in Sudden Infant Death Syndrome: The Nordic Epidemiological SIDS Study. J Pediatrics 1997; 100(4): 613-621.

[4] Kemp, J., Thatch, B., A Sleep Position- dependant Mechanism for Infant Death on Sheepskins. AJDC. 1993;147:642-646

[5] Kemp, J., Thatch, B.Sudden Infant death in Infants Sleeping on Polystyrene-Filled cushions. N Engl J Med 1991;324:1858-64

[6] The Changing Concept of Sudden Infant Death Syndrome: Diagnostic Coding Shifts, Controversies Regarding the Sleeping Environment, and New Variables to Consider in Reducing Risk. J Pediatrics 2005;116:1245-1255

[7] Paluszynska, D., Harris, K., Thatch, B. Influence of Sleep Position Experience on Ability of Prone-Sleeping Infants to Escape from Asphyxiating Microenvironments by Changing Head Position. J Pediatrics 2004;114:1634-1639

2.2.1 Breathing Control and Data Acquisition

The mechanical breathing hardware and the data acquisition hardware, as shown in Figure 2, were controlled and monitored with software written in LabVIEW 8.6.

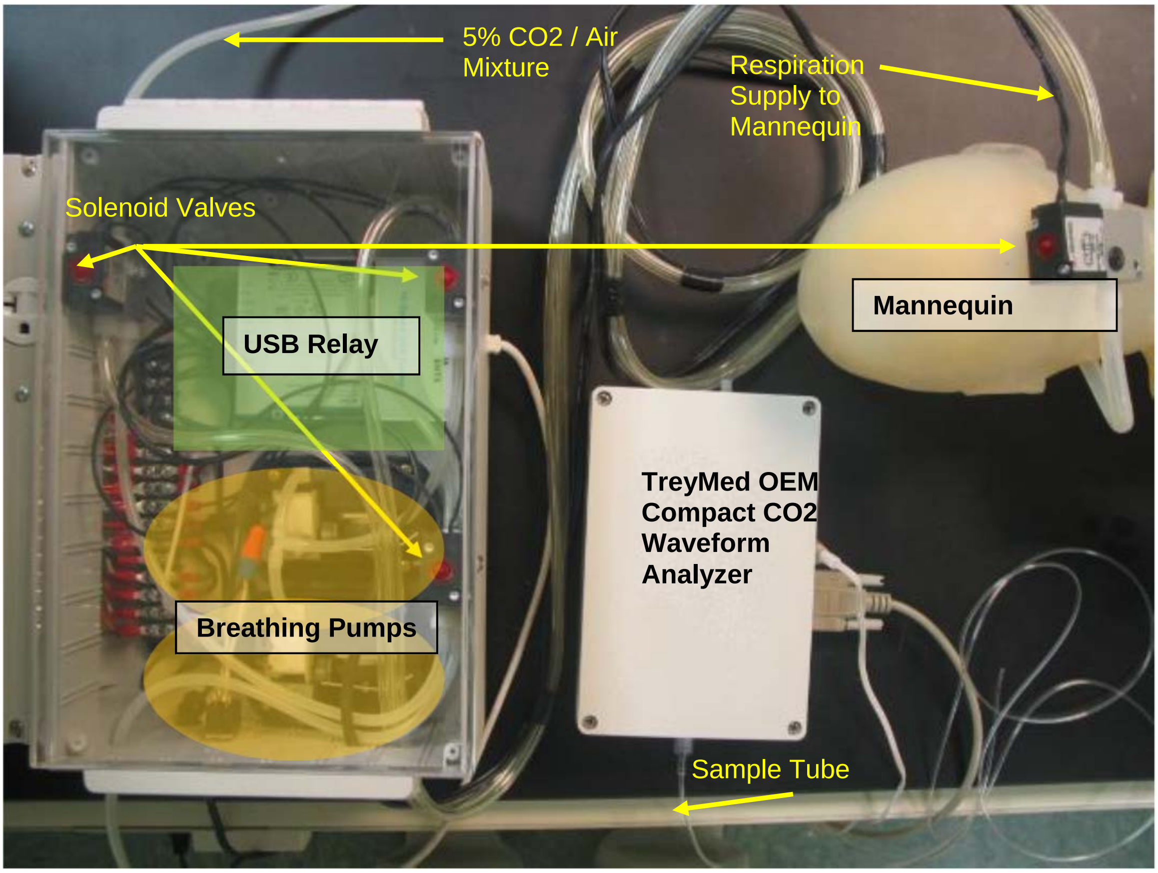

Figure 2 Carbon Dioxide Rebreathing Evaluation Hardware

The mechanical breathing hardware consists of a four channel USB controlled relay module, four 120VAC pneumatic solenoids, two diaphragm style pumps and a tank of CO_2/Air mixed gas. The solenoid valves, compressed gas, and diaphragm pumps were plumbed such that by controlling the opening and closing of the valves a simulated breathing pattern could be achieved. Each breath of the breathing pattern consisted of three parts, an inhale portion, an exhale portion, and a rest portion. The inhale portion was 45% of the cycle, the exhale portion was 45% of the cycle, and the rest portion was 10% of the cycle.

The respiration rate is in breaths per minute and can be increased or decreased by changing parameters in the control software while the flow rate is controlled by rotameters.

The data acquisition hardware used in this experiment was a TreyMed OEM Compact CO2 Waveform Analyzer. The OEM Compact CO2 Waveform Analyzer (CO2WFA) is a complete data collection and analysis system for monitoring respiratory carbon dioxide concentration. The CO2WFA module includes a miniature CO2 sensor, barometric pressure transducer, sampling flow control and a miniature low-power vacuum pump. A microprocessor collects the sensor data and calculates various real-time parameters: instantaneous CO2 concentration, respiration rate, end-tidal CO2, inspired CO2, inspiration and expiration times.[8]

The pump provided with the CO2WFA module is capable of sampling patient gas at a regulated 50-250 cc/min, and can provide some protection from occlusions in the sample line. The module automatically performs calibrations to correct for changes in temperature, altitude and electronic component drift by switching a solenoid valve from the sample line to ambient air for a few seconds

[8] *www.treymed.com*

in order to collect a reference point used in the CO2 calculation. All communications between the host computer and the module i.e. sent commands; received waveforms, breath parameters and command responses are via 3.3V asynchronous serial data lines.[9]

Human exhaled air is composed of nitrogen, oxygen, carbon dioxide and water. The sensors used in this study can be negatively affected by the presence of water; therefore, dry air was used for this study. A tank of gas with the mixture shown in Table 1 was used. Except for the absence of water, the composition is similar to that of human expiration.

2.2.2 Mannequin

The mannequin for this setup was designed to be the interface between the evaluation hardware and the product sample to be tested. It was constructed of bio-simulating materials and was plumbed with tubing simulating air passages in order to introduce and draw off the evaluation gasses into and out of a sample. Along with simulated air passages, the mannequin was constructed to be the appropriate size and weight of a child approximately one month of age. This is to provide a realistic physical interaction between the mannequin and the sample material.

2.2.3 Gas/Air Mixture

As the mannequin and the accompanying hardware breathe into the sample, the mixture of gasses that are expelled are representative of those gasses present in the exhaled air of an at-rest human; the dry gas mixture used in this evaluation is broken down in Table 1. As the mannequin inhales from the sample, the gasses that it breathes back in are a mixture of the previous exhaled gasses and the ambient room air.

Table 1 Gas Mixture for Carbon Dioxide Rebreathing Assessment

Component	Expired Air (%)
Nitrogen	76%
Oxygen	17%
Argon	2%
Carbon Dioxide	5%
Total	**100%**

2.2.4 Test Method

The carbon dioxide measurements were taken according to the following procedure:

1. Check that all preconditions are met to run experiment. Ensure that the equipment is turned on and that the software is ready to run.
2. Place sampling tubes through slit in sample proximate to the opening of the oral cavity.
3. Test parameters are entered into the software.
4. Test is initiated by operator via software.
5. Test gas is pumped into the sample at a rate of 25 breaths per minute.
6. Sample is subjected to respiration for 1 hour.
7. Sample is evaluated for its capacity to retain carbon dioxide over a 10-minute period.
8. The carbon dioxide retention and its rate of dispersal over time are plotted.
9. The area under each of the carbon dioxide vs. time curves is calculated.

2.2.5 Product Samples

This carbon dioxide rebreathing evaluation was conducted on the Mimos Pillow samples and compared to items with a known hazard level, including a firm spring mattress with sheet, sheepskin, and fabric covered polystyrene bean filled cushions (hereon referred to as bean bag). Product information for each of the comparator items can be found in the following Figure 3 to Figure 5. The comparator items were tested directly on the lab bench.

[9] *www.treymed.com*

Figure 3 Comparator Mattress with Sheet

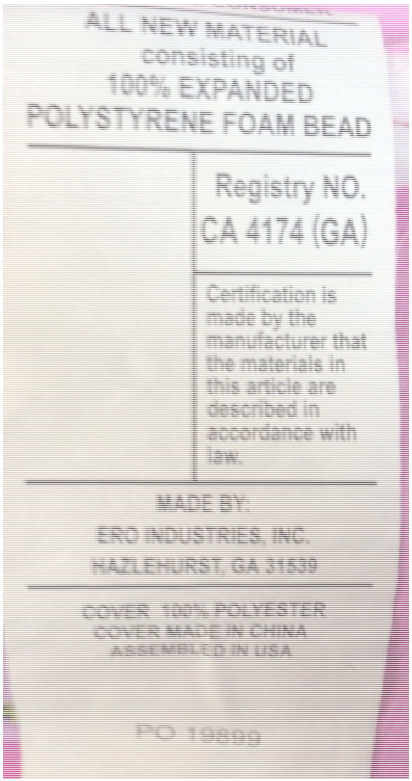

Figure 4 Comparator Bean Bag

Figure 5 Comparator Sheepskin

2.2.6 Test Setup

To determine the location of an evaluation sight, components that possess filled or partially filled volumetric characteristics are identified. Generally these filled components consist of a filling material encapsulated by a permeable or semi-permeable fabric. Also, components that can provide support but have an internal structure that contain many voids are identified. These types of components include, but are not limited to, open celled foams, dense furs and wools, or multiple layers of permeable or semi-permeable fabrics. The Mimos pillow was evaluated at different locations to identify the most significant potential area where the hazard may be at its highest level. The area shown in the following Figure 6 was selected for the study. For all experiments, the head of the mannequin was placed with its face pressed into the Mimos sample, as shown in Figure 7 through Figure 10 so as to represent the worst case scenario situation.

Figure 6 Mimos Pillow Revised Sample

Figure 7 Bean Bag Carbon Dioxide Rebreathing Evaluation Detail

Figure 8 Long Haired Sheepskin Carbon Dioxide Rebreathing Evaluation Detail

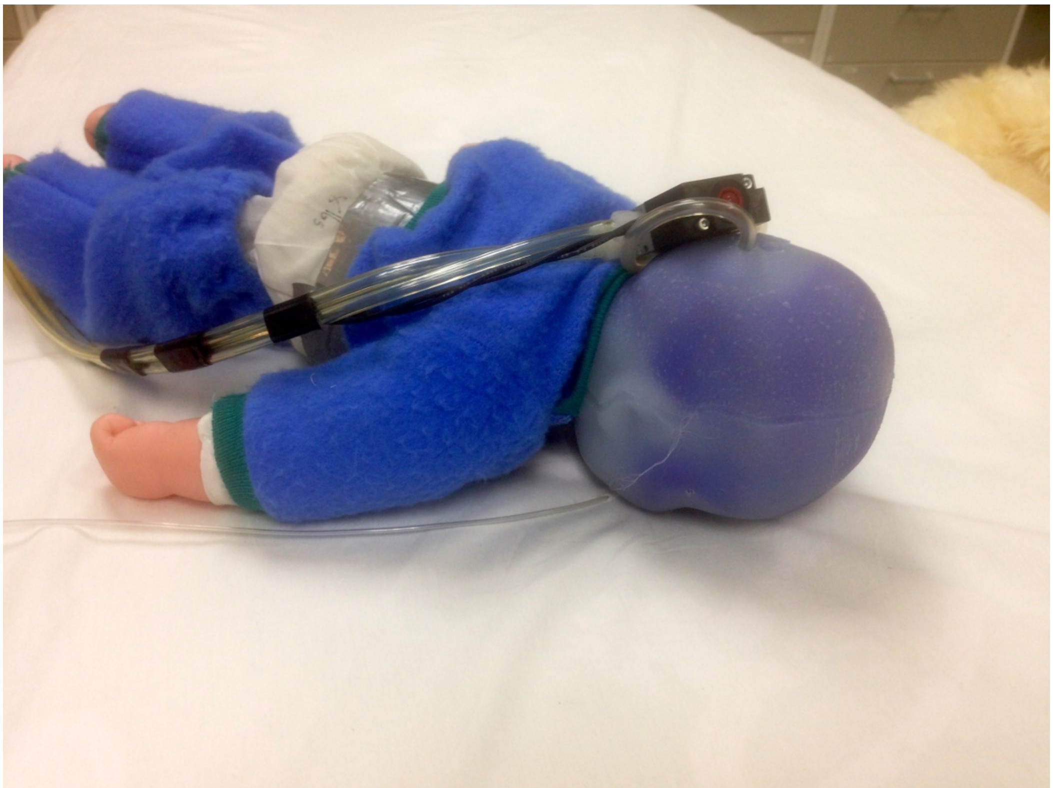

Figure 9 Firm Mattress and Cotton Sheet Carbon Dioxide Rebreathing Evaluation

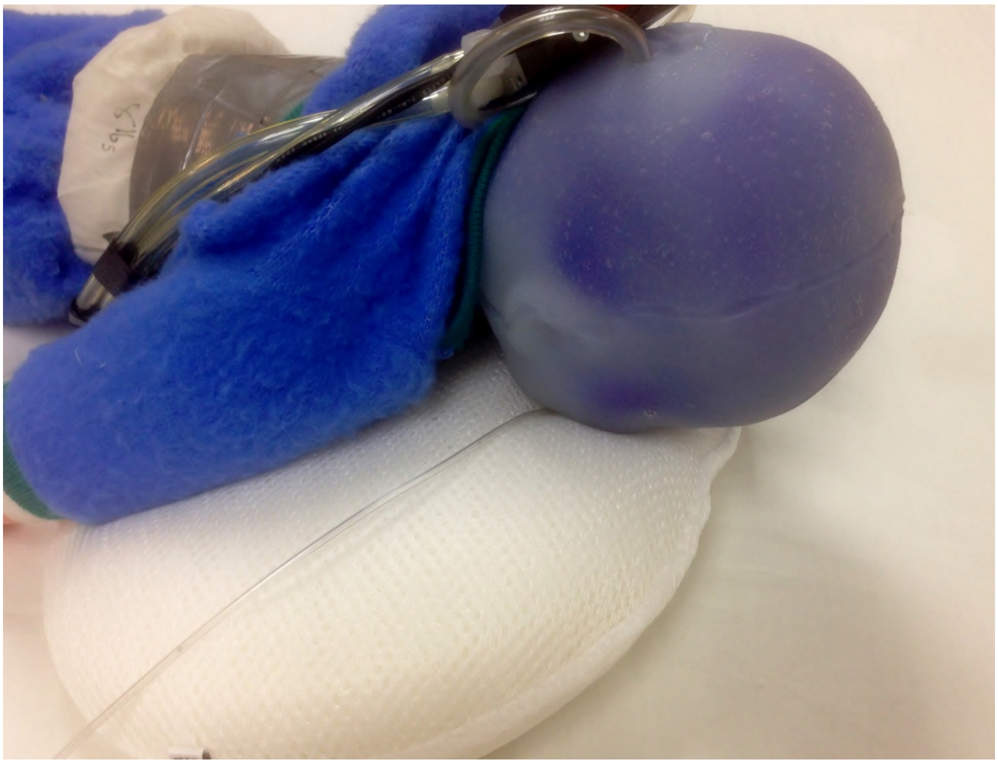

Figure 10 Mimos Pillow Revised Carbon Dioxide Rebreathing Evaluation

2.2.7 Acceptance Criteria

The carbon dioxide retention for the revised Mimos Pillow sample was compared to that of products of known high and low hazard levels. Products with high known hazard level are bean bags and sheepskin, while a mattress with a cotton sheet has a known low hazard level.

2.3 Results

The amount of carbon dioxide and its rate of dispersal over time are calculated by integrating the area under the plotted curve, results of which are shown in Figure 11 and
Table 2, for each sample and comparator product.

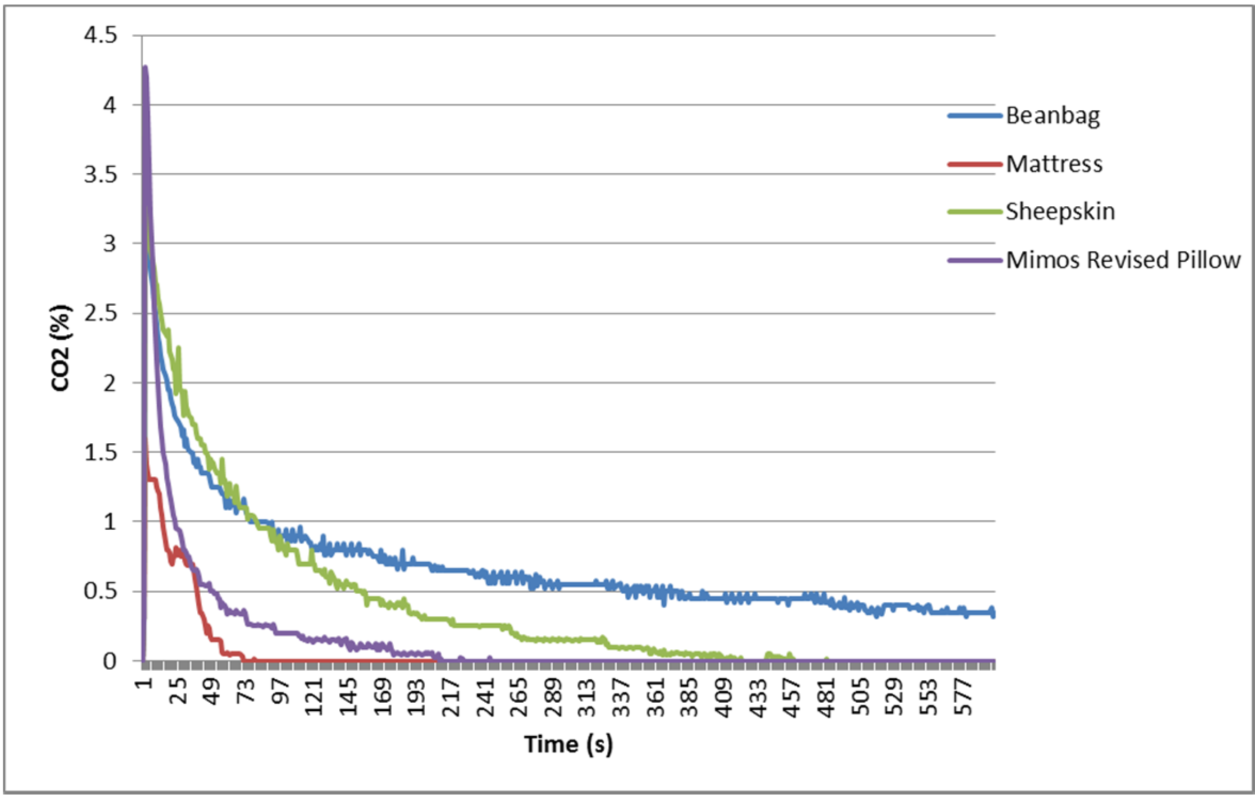

Figure 11 Carbon Dioxide Rebreathing Results

Table 2 Carbon Dioxide Rebreathing Results, Area Under Curve

Sample	Area Under Curve (%CO2)
Beanbag	415.3
Sheepskin	241.3
Mimos pillow revised	92.9
Mattress	39.5

Examining the carbon dioxide retention over time as well as area under the curve for the Mimos Pillow, the results were similar to the Sheepskin (potential high hazard level) comparator product.

The product samples were sent to Dr. William W. Fox, Division of Neonatology, Children's Hospital of Philadelphia, and Dr. Thomas H. Shaffer, Department of Biomedical Research, Alfred I. duPont Hospital for Children for expert medical opinion to confirm the level of hazard for carbon dioxide rebreathing. The results were reviewed and the following comments were received:

After looking at the data, the revised Mimos pillow "looks good" and that the revisions to the pillow functionally make it "not a reservoir for CO2".

Given the results of the carbon dioxide evaluation and the expert medical consultation, the revised Mimos Pillow does not pose a significant hazard for carbon dioxide rebreathing.