

Sleep-Related Infant Death

• SRID claims approximately 3500 infant lives annually in the U.S. [1]



Figure 1. Fisher Price Rock n' Play [2]

- Causes include:
 - Non-supine sleep position
 - Inclined sleep surfaces exceeding 10°
 - Soft bedding
 - Parental bed-sharing
 - Unsafe infant sleep products

- Unsafe infant sleep product triggered need for device:
 - Fisher Price Rock 'n Play attributed to almost 100 infant deaths
 - Inclined sleep at 30° and soft bedding → positional asphyxiation

- Safety Standard for Infant Sleep Products issued June 23, 2022
 - Manufacturers required to adhere to safe sleep recommendations
 - Sleep products cannot exceed 10° inclination

- Goal: Outfit existing silicone infant model with sensors to quantify unsafe sleep scenarios according to American Academy of Pediatrics (AAP) Safe Sleep Guidelines**

Design Basis



Figure 2. Common Unsafe Infant Sleep Scenarios and Suffocation Risks [1]

Incorporated Sensors and Questions Addressed

AAP Guidelines	Sensors	Questions Addressed
Supine position- Back to sleep every sleep	Gyroscope Sensor (A)	• Is the infant on its back?
Use firm, flat, non-inclined sleep surface	Gyroscope Sensor (A) Linear Hall Sensor (B)	• Is the infant on an inclination? • Chin to chest? Airway collapsed?
No soft or weighted objects on or near sleeping infant	Photoresistors (C) Load Cell (D)	• Objects covering nose and mouth? • Is there weight on the chest?
Sleeping in the same room, but no bed-sharing	Photoresistors (C) and Load Cell (D)	• Did a parent roll over on the infant?

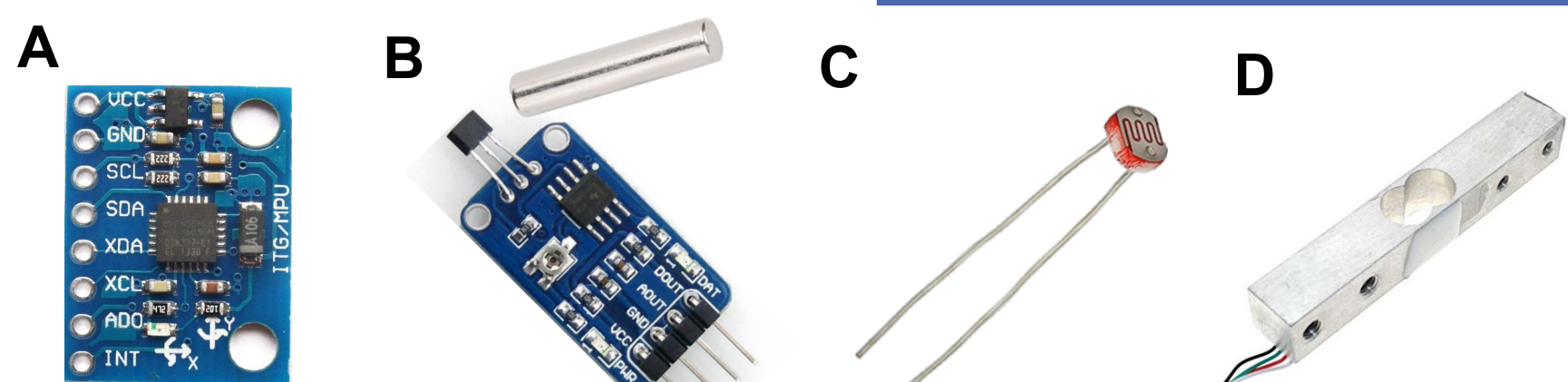


Figure 3. Incorporated Sensors (A) Gyroscope (B) Linear Hall (C) Photoresistors (D) Load Cell

Embodiment of Design

CAD Models of Infant Sleep Testing Device

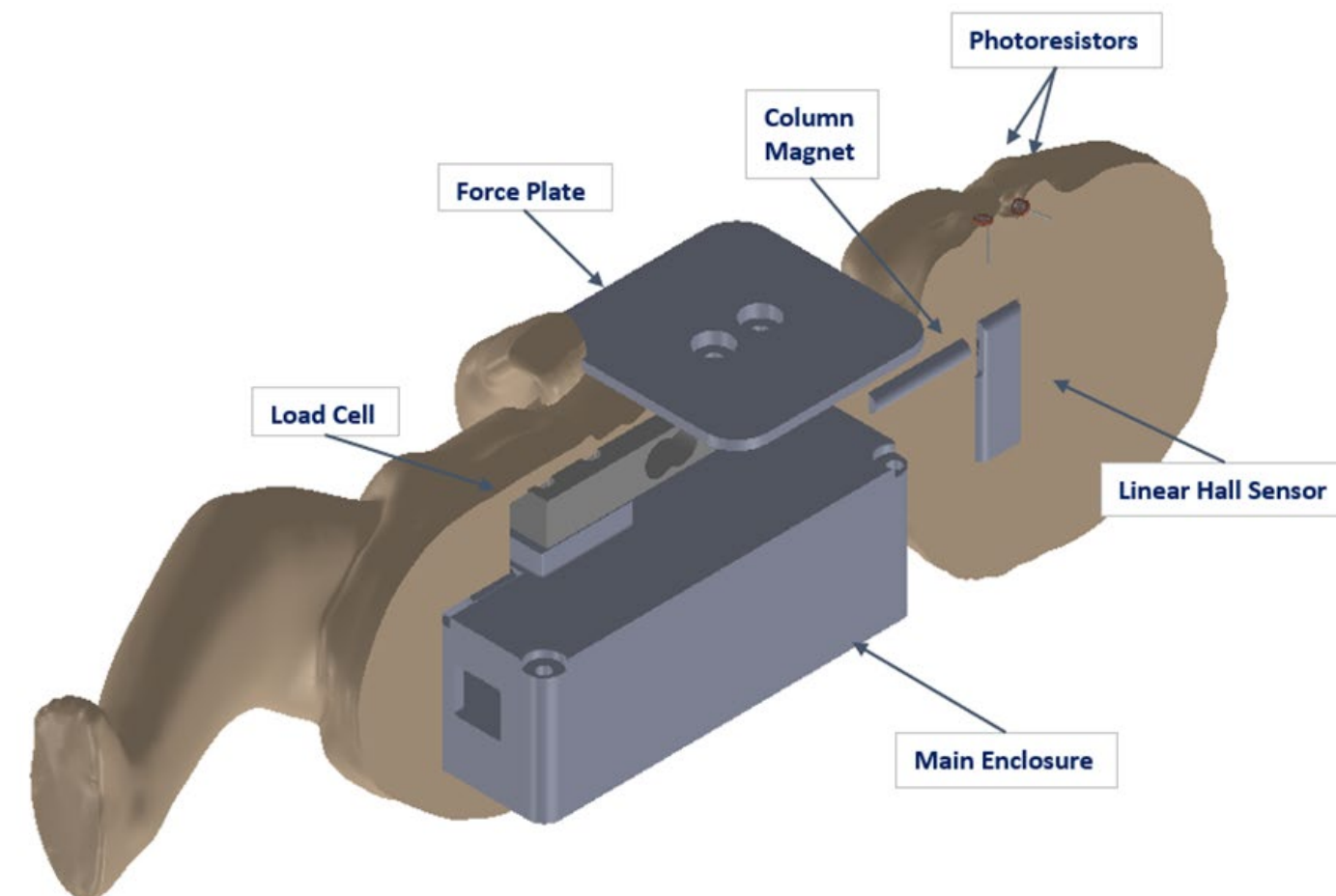


Figure 4. CAD Model of Sleep Testing Device in Silicone Infant

Test Device Characteristics

- Model created from 00-31 silicone using 3D printed custom mold
 - Creates more accurate neck flexure
- Custom mold insert fabricated to correlate with enclosures
- Enclosures were developed in SolidWorks and 3D printed with PLA
- Wired connection from Arduino UNO Rev3 to PC

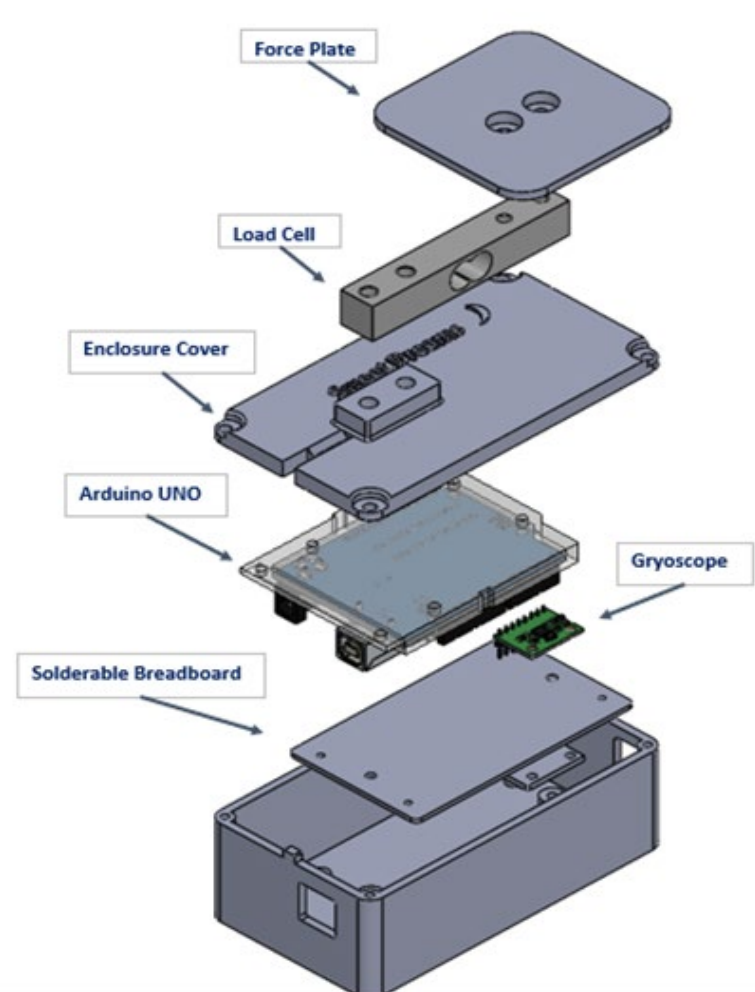


Figure 5. Exploded View of Internal Circuit Housing

Circuit Components

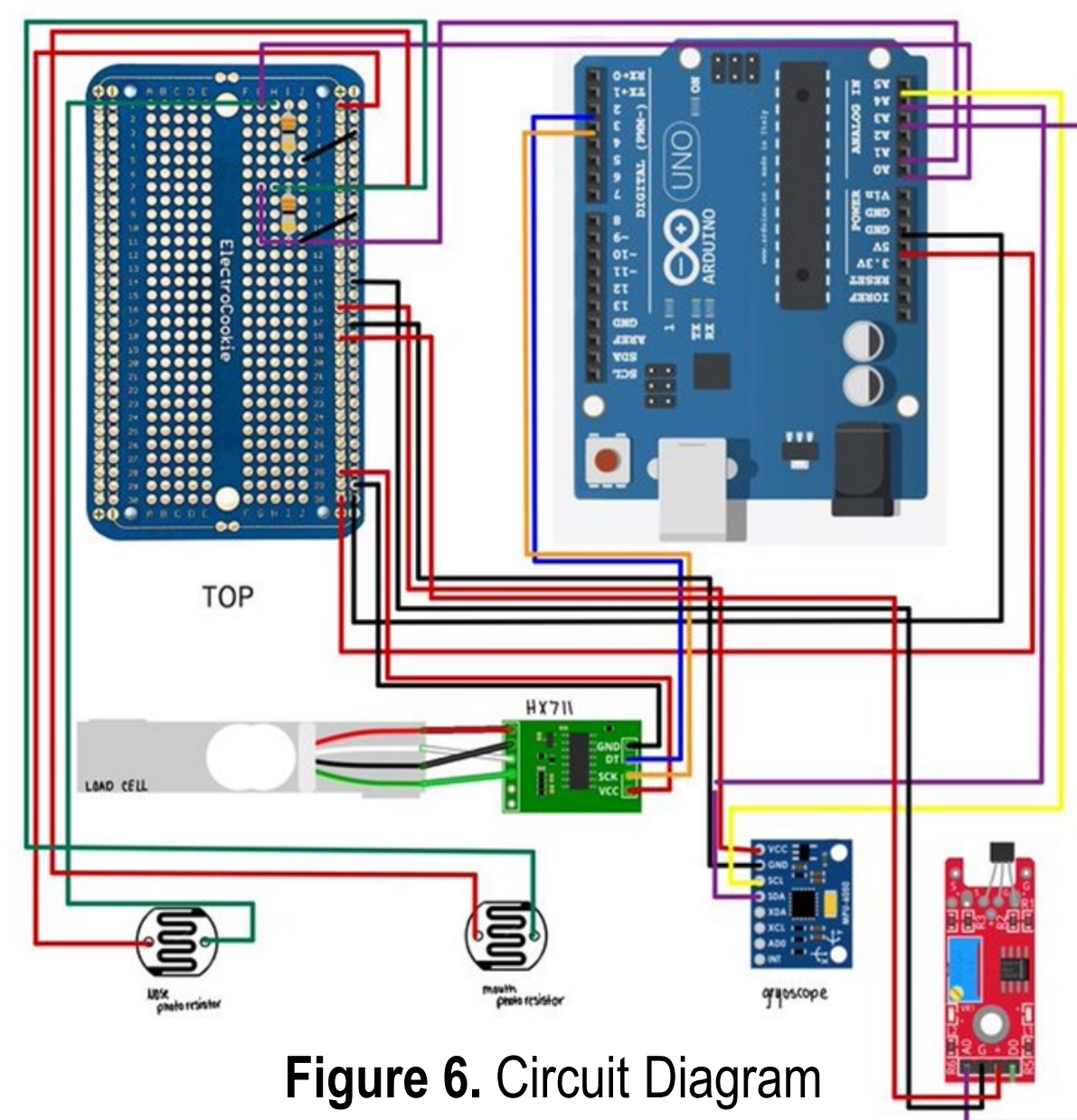


Figure 6. Circuit Diagram

Circuit Characteristics

- Arduino UNO Rev3 to ElectroCookie Solderable Breadboard
 - Arduino 5V connection powers positive rail on breadboard
 - Arduino ground connection to negative rail on breadboard
- All sensors were external to main housing except gyroscope and HX711 amplifier for load cell
- Arduino IDE software used to code sensors and user-interface system for data output

User Interface

Figure 7. PLX-DAQ Control Panel. Allows raw data collection on degree of inclination/rollover, chest weight, nose/mouth blockage, and airway blockage via direct connection to Excel.

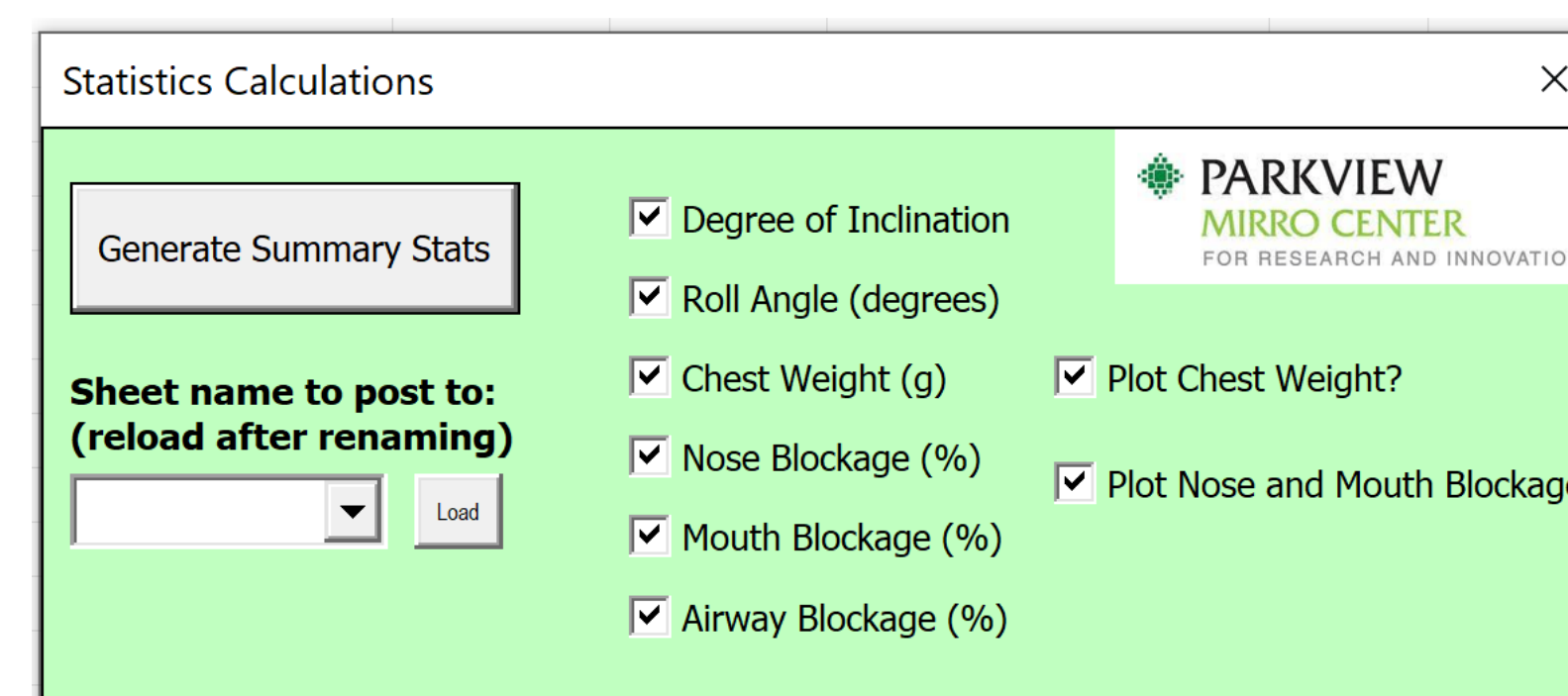
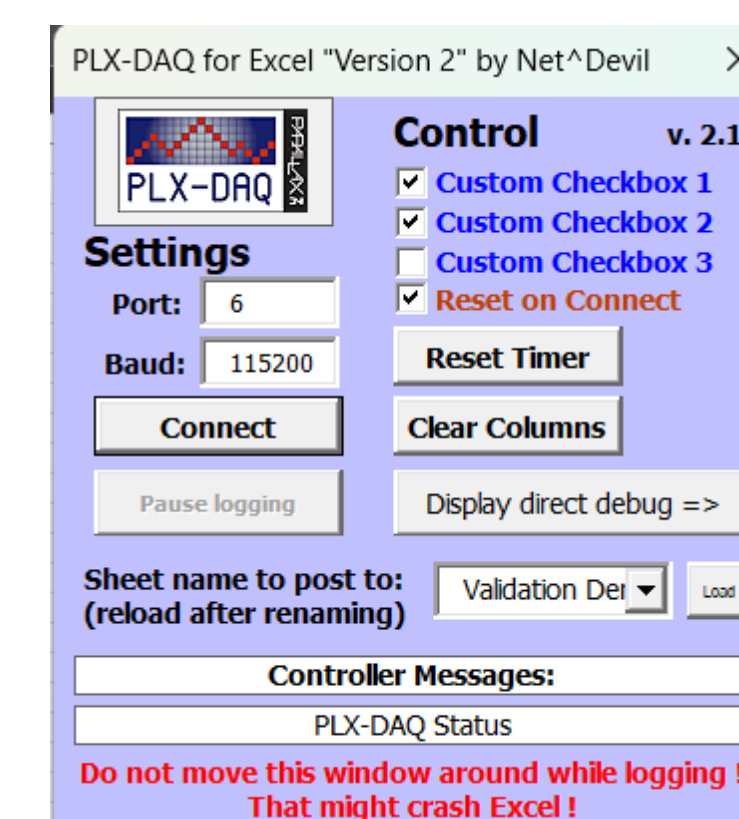


Figure 8. Summary Statistics Control Panel. Summarizes raw data by measurement and calculates the *minimum*, *average* and *maximum*. Applies pass/fail designation based upon AAP safe sleep guidelines and physician recommendations.

	Min	Average	Max	Validation per 2022 AAP Safe Sleep Guidance		
				Min Pass/Fail	Average Pass/Fail	Max Pass/Fail
Degree of Inclination	-4.67000008	-2.14288473	-1.66999996	Fail	Fail	Fail
Degree of Rollover	-8.82999992	-8.02826881	-6.76200023	Pass	Pass	Pass
Chest Weight	-2.33999991	140.8267365	1333.5400039	Recalibrate	Pass	Fail
Nose Blockage (%)	0	3.862692356	26.71999931	Pass	Warning: Blockage Detected	Warning: Blockage Detected
Mouth Blockage (%)	0	5.189423084	26.19000053	Pass	Warning: Blockage Detected	Warning: Blockage Detected
Airway Blockage (%)	0	0	0	Pass	Pass	Pass

Figure 9. Example of Summary Statistics With Pass/Fail Designations

Verification Testing

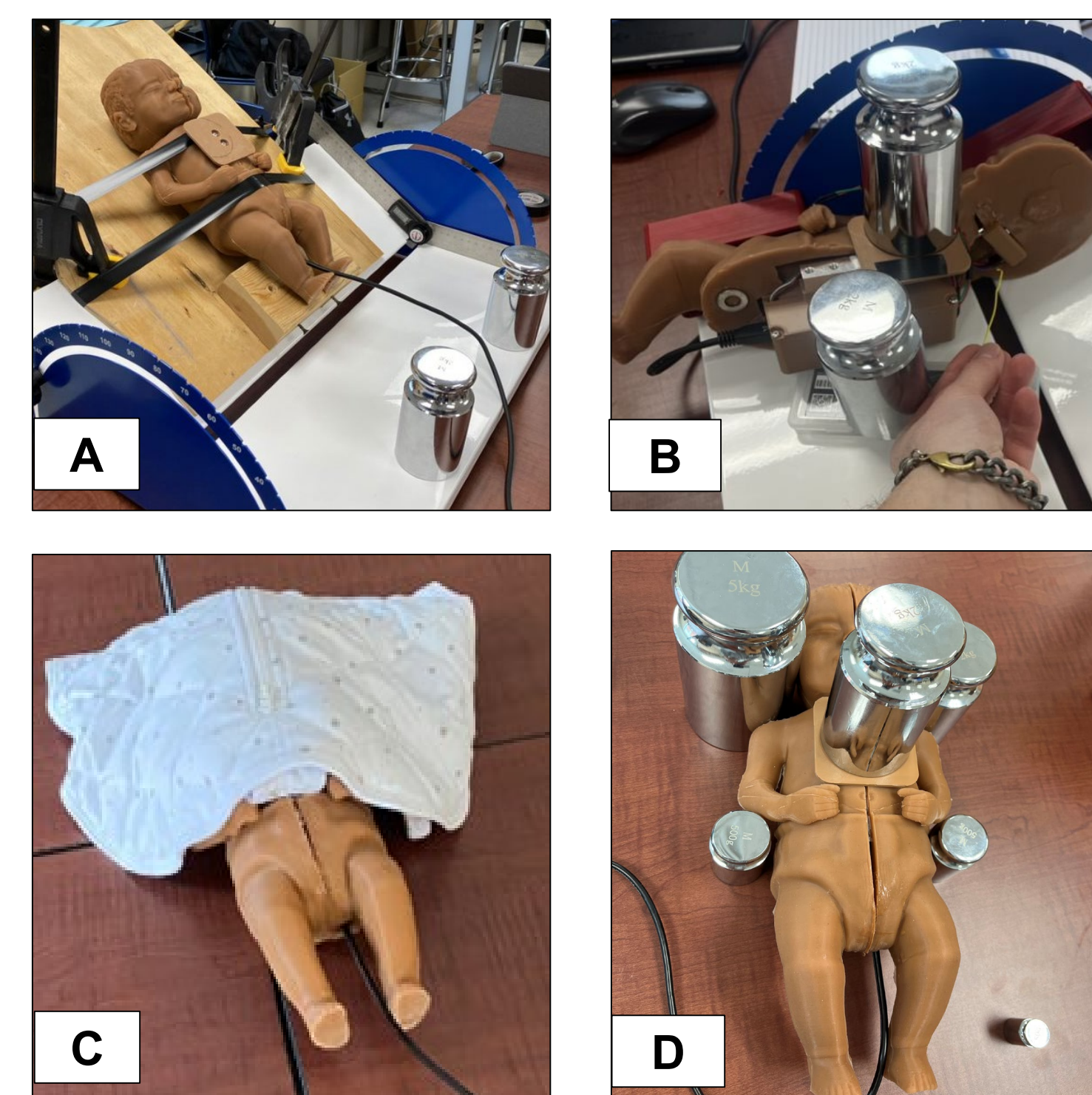


Figure 10. Verification Testing Results (A) Gyroscope Test: Passed all accuracy and repeatability specifications except rollover angle extremes. (B) Linear Hall Test: Passed fully open and slightly closed blockages but failed higher blockage conditions. (C) Photoresistors Test: Light sensors can measure orifice blockages with 100% accuracy and repeatability (D) Load Cell Test: Passed all accuracy and repeatability specifications.

Conclusion and Future Vision

Conclusion

- Device successfully quantifies sleep-related measurements
- Device can prevent market release of unsafe sleep products
- Device use for sleep product certification may reduce SRID

Future Vision

- Functional improvements
- Improved device aesthetics
- Pursuit of AAP Endorsement
- Mandatory Use By Sleep Device Manufacturers



Figure 11. Prototype Testing Infant



Figure 12. Future Vision: Happy, Healthy Babies Safe at Sleep [3, 4]

References

- [1] R. Y. Moon, R. F. Carlin, and I. Hand, "Evidence base for 2022 updated recommendations for a safe infant sleeping environment to reduce the risk of sleep-related infant deaths," *Pediatrics*, vol. 150, no. 1, 2022.
- [2] J. Hernandez, "Fisher-Price ignored safety warnings even after infants started dying, report finds," *NPR*, 07-Jun-2021. [Online]. Available: <https://www.npr.org/>.
- [3] "What do our safe sleep recommendations mean?," Red Nose Australia, 07-Mar-2020. [Online]. Available: <https://rednose.org.au/article/what-do-the-safe-sleep-recommendations-mean>.
- [4] M. Masters, "When will your baby sleep through the night?," *What to Expect*, 23-Feb-2022. [Online]. Available: <https://www.whattoexpect.com/first-year/sleeping-through-the-night.aspx>.

Acknowledgments

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