



# DaySense

Empowering Kids, One Step at a Time

## New Product Development

January 2025 - April 2025

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Apr 21, 2025

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### Executive Summary

Diurnal enuresis is defined as accidental urination that occurs at least twice a week for at least three consecutive months in pediatric children aged 5-17, and can cause a variety of social, emotional, and physical challenges for patients and their families, which are exacerbated in patients with ADHD. Current solutions for enuresis lack a combination of accident prevention mechanisms with behavioral training, as well as mainly being geared towards the nocturnal enuresis market. The DaySense addresses this market gap by providing a three-system solution: biometric tracking through the SenseBand, the DaySense AI for enuresis prediction, and interactive behavioral training through the DayWatch. An initial prototype was designed for the DaySense system that features patient leg movement and heart rate data tracking to predict diurnal enuresis accidents, component communication to integrate Machine-Learning (ML) predictions with a front-end interactive display, and a Tamagotchi-style game to facilitate behavioral training. Formative and verification testing results show promise in utilizing biometrics to prevent enuresis and being able to effectively track these biometrics through hardware components integrated into the SenseBand, while usability studies unveiled key room for improvement in the Graphical-User Interface portion of the DayWatch system. Through these testing efforts, analysis of the current market of solutions for diurnal enuresis, and understanding of areas for potential expansion, it was determined that the DaySense provides a clear value proposition to address the unmet clinical need for a method to predict diurnal enuresis accidents before they occur in pediatric patients with enuresis and ADHD.

## I. Clinical Problem and Product Opportunity

### Description of the Problem

*Clinical Definition.* Enuresis is accidental urination that occurs in children aged 5-17. It is clinically diagnosed when a pediatric patient accidentally urinates at least twice a week for three consecutive months. It can occur during the day, which is defined as diurnal enuresis/daytime urine incontinence, or at night, which is commonly referred to as “bed wetting” or nocturnal diuresis[1]. It occurs when bladder reservoir function is disrupted, and the detrusor muscle contracts while the urinary sphincter relaxes with a filled bladder[2]. This can be caused by a variety of reasons including, but not limited to: sleep-arousal disturbances, bladder detrusor or sphincter muscle dysfunction, abnormal bladder reservoir function, genetic predisposition, developmental delay, abnormal circadian rhythm of antidiuretic hormone, and psychosomatic manifestation[3].

*Associated Challenges.* Enuresis causes a multitude of challenges in patients. Emotionally, patients with enuresis report lower self-esteem scores when compared to patients without enuresis[4]. Additionally, 34.6% of children with enuresis are shown to develop anxiety, as opposed to only 10% for all children, representing a co-incidence rate that is over three times higher[5]. Enuresis also results in social challenges for this population of patients, with pediatric enuresis patients displaying conduct disorders at a rate twice as high as patients without enuresis(10.8% vs 5% , respectively)[6]. They are also almost three times (2.88x) more likely to develop Attention Deficit Hyperactive Disorder(ADHD) compared to children without enuresis[7]. For patients with ADHD, enuresis is also more prevalent by 2.7x compared to the general pediatric population[8]. For kids with ADHD, these enuresis accidents can be even more difficult to manage and treat, due to these patients having more trouble noticing and understanding their own body’s needs and being able to effectively respond to impending accidents. As such, these patients experience exacerbated symptoms of enuresis compared to other enuresis patients. Enuresis can also cause financial challenges for families, with the cost for managing and treating enuresis for families estimated to be roughly \$1,715/year[9].

### Stakeholders

The stakeholders for the enuresis market include: children between the ages of 5 and 17, the caregivers of these children with enuresis, doctors and therapists who care for these children, hospital systems that offer treatment for enuresis, and the commercial market that produces and sells current solutions that are designed to manage symptoms of enuresis.

### Competing Technologies and Assessment

If a child experiences bed-wetting, the first step of treatment is bathroom training or limiting liquids and using the restroom before bed. If the problem continues to persist, device solutions or behavioral training may be used[10].

*Device Solutions.* The most common device solution is alarm therapy. Alarm therapy works by detecting moisture in the child’s undergarments and setting off an alarm to wake the child. This eventually creates a behavioral change in the child to wake up when feeling the need to urinate. The downsides of this treatment, however, are that it takes a long and consistent effort in order for it to be effective, as well as it does not always work, with a 68.8% success rate. This leads to a dropout rate of up to 30%[11].

Additionally, since this treatment only detects bed-wetting after it has already started, it does not work in preventing it from happening in the short-term, and is not effective for daytime enuresis. Another common device solution is the GoGo Band, which tracks biometrics such as heart rate, blood pressure, skin conductivity to alert a user of an upcoming accident. However, this device is not FDA approved and can only be used for nocturnal enuresis[12].

*Behavioral Training.* Children can also engage in behavioral training, where an external method of progress tracking is used to indicate when they have accidents or when they successfully prevent accidents. This method of treatment is intended to have patients gain understanding of their body’s needs and learn how to manage enuresis on their own. The most common method for this is the star reward chart, where a child receives a star sticker for everyday they go without an accident and after a certain

amount of stars collected, they receive a reward. While this method is effective at helping patients visualize their progress, it requires the guidance of a caretaker or supervisor and doesn't involve any detection or prediction mechanism for managing enuresis[13].

### Clinical Need

Due to the exacerbated enuresis symptoms experienced in enuresis patients with ADHD and the increased likelihood of both occurring at the same time, our solution will be geared towards this subsegment of patients. As such, we have identified that there is a need for a way to predict diurnal enuresis accidents before they occur for pediatric patients with enuresis and ADHD to prevent social, emotional, and financial challenges associated with enuresis.

### Our Solution

The DaySense is a system of 3 components, the SenseBand, the DayWatch, and the DaySense Artificial Intelligence (AI). It utilizes multi-biometric tracking with a gamified user interface that is kid-friendly. *SenseBand*. The wearable unit, composed of an accelerometer and a heart rate monitor, is placed on the patient's knee using a flexible, adjustable strap to track lower body user movements. The accelerometer unit is capable of measuring leg orientation, while the heart rate monitor tracks the user's heart rate.

*DayWatch*. The DaySense watch module features an gamified graphical user interface (GUI) that notifies a patient when an enuresis accident is soon to occur. This entails a haptic buzzer alert as well as an image based alert on the watch to use the restroom. The alert is image-only to make the interface as accessible as possible for younger children who may not be able to read yet. The watch will also incorporate a Tamagotchi-style game which rewards the user for taking care of the enuresis. Upon using the restroom, the user will receive an increase on the accident tracking bar that records how many accidents have been avoided by the user. Upon meeting certain milestones of days without an accident, the user will receive a reward for their in-game character. This will encourage better behavior and adherence to their enuresis treatment and minimize their embarrassment. To note, DaySense will only incorporate positive reinforcement techniques in order to avoid discouraging the user through negative reinforcement and leading to poor adherence to their enuresis treatment.

*DaySense AI*. There is an integrated ML module built into the SenseBand that processes movement and heart rate data to alert the patient through the watch component, DayWatch, of an upcoming enuresis accident. This module continuously takes in patient motion data and heart rate data over the course of a two-week training period to analyze and understand the patient's daily movements, and uses a binary classification method to determine whether leg movements are representative of everyday motion or in response to the need to void. This training period will require the user to press a button on the watch module each time they void to train the ML algorithm. Following this training period, the algorithm then continuously tracks the patient's data and uses information gathered in the training period to determine when a patient's movements are representative of an upcoming enuresis accident. Upon determining the user needs to use the restroom, the module will send a wireless alert to the watch module.

### Intended Use and Indications for Use

*Intended Use*. DaySense is intended to predict diurnal enuresis accidents and alert patients before these accidents occur.

*Indications for Use*. DaySense is indicated for use by pediatric patients with both enuresis and ADHD to reduce diurnal enuresis accidents and facilitate behavioral training such that patients are able to independently recognize their body's signals and react to prevent accidents

### Value Proposition

Our DaySense system helps children who have ADHD and experience diurnal enuresis and their caregivers who want to manage symptoms of enuresis and find a solution to stop accidental urination by providing a method, using biometric tracking and a ML algorithm, with which they can predict potential impending urinary accidents during the day and presenting this method in a kid-friendly way to the

children who are having urinary incontinence through gamified reward based behavior training on a wearable watch unlike our competitors who do not provide predictive management methods for enuresis separately nor in conjunction with behavioral training methods.

### **Target Population & Market Opportunity**

*Target Population.* Based on the clinical criteria for diagnosis of diurnal enuresis or daytime urinary incontinence and underserved segments of this market, DaySense's initial target population is children between 5 and 17 years of age with both diurnal enuresis and ADHD within the U.S., as this is where we first plan to receive regulatory approval and reach market. Given that the reported population for children aged 5 to 17 in the U.S. was 49.6 million, the prevalence rate of ADHD in this age range, according to the CDC, was 11.3% in 2022, and that 5% of children have both enuresis and ADHD, the target population was determined to be 275,000 pediatric patients with enuresis and ADHD [14], [15], [16].

*Total Market Opportunity.* Our main competitor, the GOGO Band is priced around \$500 with additional subscriptions fees. It was determined that families would be willing to pay a premium for the DaySense for its predictive algorithm and daytime use. As such, the DaySense was priced at \$750. Applying this price to the target population of 275,000 children with enuresis and ADHD, the total market for the DaySense is estimated to be \$206.25 million. In the future, DaySense anticipates expanding to the nocturnal enuresis market (\$1.03B) and then further to the general toilet training market (\$18.53B)[15].

### **IP Landscape & Strategy**

From our IP landscape research, we found that the GOGO Band's patents pose the most overlap with our technology. The GOGO Band has 3 patents that we made sure not to infringe: US-11430245-B2, US-10905368-B2, and US-10685249-B2. Details of these patents as well as other IP that are applicable to our technology are included in Appendix 4. "IP Landscape". Our overall Intellectual Property(IP) strategy will be to protect our most unique feature which is the use of the accelerometer movement data and heart rate data combined with ML to predict when a user is experiencing signs of an impending incontinence incident, in other words, doing the "wiggle dance". As far as we can find from our extensive IP search, we cannot find any other products who have used the combination of movement data, heart rate, and ML to predict future enuresis accidents. In addition, the general idea that a "wiggle dance" can be used by a technology device as the primary predictor for an onset of an enuresis accident is a very novel idea that has not been explored by any other companies based on our IP research. This approach has long been used by humans to help kids avoid enuresis accidents (i.e. parents encouraging their kids to go to the bathroom when they see the kids doing the "wiggle dance"), however, the same approach has not been implemented using technology. Therefore, we believe DaySense's technology that will serve as the "wiggle dance sensor" will be the most crucial IP to protect. For freedom-to-operate (FTO) considerations, it is important to avoid certain primary claims made by competitors while focusing on products most similar to DaySense, such as GOGO Band, Apple Watch, Tamagotchi, and Progress Pyramid. Specifically, GOGO Band's use of ultrasound or photo-sensing technology for tracking bladder fullness or volume as the main mode of enuresis prediction should be avoided. Regarding the Apple Watch, leveraging accelerometer data in conjunction with audio for behavior prediction should not be utilized, though their technology is used to predict handwashing and not impending enuresis.

Tamagotchi's concept of nurturing a virtual character that grows and matures should be avoided, though its patent has expired. Additionally, any approach that modifies behavior through discipline should not be incorporated. From a patentability and IP perspective, there is potential for a novel patent approach that relies solely on accelerometer and heart rate data with ML to predict daytime enuresis, without the use of ultrasound, moisture sensors, or timers.

## II. Quality and Design Control

### User Needs and Design Requirements

Critical user needs and design requirements for the DaySense are shown in Table 1. [17]

User Need	Design Requirement
Solution should alert patient of an enuresis accident before it occurs	Solution predicts accident $\geq 10$ minutes before it occurs
Solution should alert patients with high levels of accuracy and specificity to limit confusion	Solution predicts accidents with $\geq 75\%$ accuracy
	Solution predicts accidents with $\geq 60\%$ specificity
Solution should alert patients in a timely manner	Solution alerts user 10 minutes ( $\pm 5$ ) before potential accident
Solution should not be over-stimulating [18]	Vibration alert complies with IEC 60601-1/ISO 9241-940 [18]
Solution is easily interpretable by pediatric patients	GUI is image-based & uses universal icons
Solution should be discrete and not reveal patient's enuresis diagnosis[19]	Solution compatible with standard clothing/accessories [19]
Solution should promote behavioral training for patients to go to the bathroom on their own	Reward granted at consistent intervals
	GUI promotes adherence rate $\geq 60\%$
Solution should be portable	Solution complies with IEC 62366 [17]

Table 1. Critical User Needs and Design Requirements for the DaySense

User needs were determined through conversations with the team's clinical mentors on what is desired by patients and performing gap analyses on what is lacking in current solutions for diurnal enuresis. Design requirements were formed through a combination of clinical feedback and consensus standards. These requirements were deemed to be critical as they relate to patient safety by either addressing the efficacy of the solution's alerts or its efficacy in promoting behavioral adherence, both of which focus on limiting the number of accidents a patient will experience.

Non-critical user needs and design requirements for the DaySense are shown in Appendix 5.

### Prototype Development

Schematics for the DayWatch and SenseBand are shown below in Figure 1.



Figure 1a and 1b. Drawings for the SenseBand (left) and DayWatch (right)

ML prototyping followed two stages: an  $\alpha$  and  $\beta$  stage. The  $\alpha$ -prototype involved a supervised ML setup, where labelled datasets were used for model training and testing. This prototype showcased the potential for biometric tracking in characterizing enuresis incidence. The  $\beta$ -prototype involved an unsupervised ML setup, where datasets with continuous biometric tracking and labelled time points for

accidents were used for model training and testing. This prototype was developed to evaluate how the DaySense alert system would function in real-time and how effective it was. These prototypes and calculated results are shown in TP00001v2.0.DaySense-MLPipeline.ipynb under Appendix 2. *DayWatch*. The DayWatch prototype is shown below in Figure 2.



Figure 2. DayWatch Prototype

This prototype includes a 3D printed case to hold electronic components, a display to display images to the user, and buttons for user interaction. This prototype was developed to show a dynamic display that would change in regards to differing sensor inputs.

*SenseBand*. The SenseBand Prototype is shown in Figure 3.



Figure 3. SenseBand Prototype

Although not integrated with the DaySense AI, the DayWatch would change to a yellow color to indicate impending enuresis in response to SenseBand movement that simulated enuresis, and would change to green when the user pressed the green button to simulate going to the bathroom. A silicone band was attached to this display case to secure onto the patient's wrist. These prototypes provided a rudimentary interface for ML and GUI integration, and their communication can be seen under Appendix 2.

*GUI*. The GUI for the DayWatch was prototyped through a Figma interface. This prototype was developed in order to show the logical flow through which a user would interact with the device for enuresis behavioral training. This prototype involved a Tamagotchi-style character named Eugene that would fill up with a rising water level and appear increasingly distressed over time to simulate an increasing timeframe over which the patient didn't use the restroom, making them more likely to experience an enuresis accident. It also featured an interactive user interface for which the user could click to indicate they used the restroom, at which point Eugene would reset to his normal level. It also included a reward system feature that would unveil a gift for Eugene after the user had simulated going to the bathroom enough times without experiencing an accident. This prototype was used in usability studies to evaluate how interpretable a GUI would need to be for pediatric users. This interface can be seen in Figure 4 below.



Figure 4. DayWatch GUI Prototype

A video demonstration of the logic flow can be found under Appendix 2.

### Verification-Testing

A partial traceability matrix showing device verification methods and results along with the specifications they map to are shown in Figure 5, with completed tests being highlighted in green. The full matrix can be found under Appendix 2.

Design Specification	Verification Method	Verification Result
-At least 75% of all enuresis accidents in a 24 hour time span are predicted by the solution -Of all alarms generated by the solution, at least 60% should be indicative of a true impending enuresis accident (as opposed to a false alarm)	Testing done in accordance with TP00001v0. -Biometric sensor data and enuresis accident time points will be collected over 24 hour time span to train ML algorithm -Additional 24-hour sensor data will be collected to test algorithm -ML outputs will be compared to test control outputs	<b>PASS</b> ML predictions achieve at least 75% accuracy ML predictions achieve at least 60% accuracy
Accelerometer measurements vary by +/- 5 degrees across all orientations	Orient accelerometer at 0, 45, and 90 degrees along the knee and measure outputs across each orientation	All measurements differ by at most 5 degrees
Heart rate measurements are within 15 BPM of true value	Measure heart rate and compare to medical grade heart rate monitor	All measurements are within 15 BPM of true value
-There shall be no condensation on the internal surface of the watch, as revealed by the condensation test performed in accordance with 4.2 and carried out before and after the test described in 4.3.3. -No air bubble should form inside of the watch at 5 ATM water pressure.	Test standards outlined in ISO 22810:2010(E) 4.3.3 -Will test only on watch component of device	Pass/Fail -No water bubbles formed in water resistance test -No condensation form in water condensation test
-All GUI icons are correctly interpreted by 90% of users -GUI prompts do not include images	Show test user Figma demo icons in sequence and prompt for interpretation of icon's function/purpose/meaning. Record responses Walk through Figma with explanations. Request rating on 1-5 Likert scale for each significant screen/icon of GUI.  -Take average of individual image Likert ratings to get overall GUI rating. -GUI Figma Mockup/demo will be used	<b>Fail</b> -Pass: At least 90% of users give accurate responses to icon recognition/interpretation prompt & at least 90% of users give an average rating of 4+ on 1-5 Likert scale. -Fail: Success criteria above not met.  <b>Pass</b> -Pass: Material does not turn white when pinched -Fail: Material turns white when pinched
Watch band and sensor band material must be non-toxic and ISO 10993 compliant	Pinch test will be performed on the watch and sensor band for silicone material	

Figure 5. DaySense partial traceability matrix

*DaySense AI.* The DaySense AI was tested to evaluate model efficacy in predicting enuresis accidents when biometrics were tracked continuously. Heart rate data and accelerometer data was tracked for 12 hours for 3 subjects with each subject collecting two datasets, one for model training and one for testing. Then, an unsupervised ML pipeline was established that used an autoencoder neural network with hyper-parameter tuning for training on one of these datasets, and then this trained model was tested following the test protocol outlined in TP00001, which can be found in Appendix 2. Test success criteria was defined as the model achieving at least 75% accuracy and 60% specificity when compared to real-time enuresis accidents across all subjects. This criteria was met for all subjects, meaning this verification test resulted in a success. Full results are shown under Appendix 2.

*Hardware.* Hardware verification testing was done in accordance with TP00002 and TP00003, as referenced in Appendix 2. To test the heart rate sensor in the SenseBand, heart rate readings were taken across 5 subjects and then compared to baseline readings taken from an Apple Watch. Success criteria was defined as the sensor readings differing from the baseline readings by no more than 15 BPM, which was achieved across all subjects, as shown in TR00002\_01-TR00002\_05 referenced in Appendix 2. Similarly, the SenseBand accelerometer unit was tested by orienting it 0, 90, and 180° in the x-axis and recording the measured orientation, and then repeating this process for the y and z axes as well. Success criteria here was defined as the measured orientations differing from the true orientations by no more than 5°. This criteria was met across all orientations, as shown in TR00003\_01 referenced in Appendix 2.

*Usability Testing.* Usability testing was performed on the GUI prototype to evaluate clarity and interpretability of GUI elements and process flow. Users were first shown images of the various elements in the prototype and asked to describe their interpretation of the purpose of each element. Responses were then analyzed and categorized as accurate or not for each element. Success criteria for this test was defined as a user defining every element accurately, with the goal of having at least 90% of all users accurately detail each element. This criteria was not achieved, as fewer than 90% of users were able to accurately identify the alert, alert response, and progress bar. A visualization of this is shown under Appendix 2.

Users were then given the Figma prototype and asked to rate the clarity of various features of the GUI as shown in UserFeedbackForm2.pdf in Appendix 2. Success criteria here was defined as a user averaging at least a 4 across all responses, with the goal being all users achieving this criteria, which was met. This test protocol is detailed under TP00004 v1.0, with results being detailed under TR00004 v1.0\_1-TR00004 v1.0\_7, under Appendix 2.

### III. Risk Management

The key hazards identified were electricity, heat, failure of the alert system, broken casing, flashing images in the GUI, and cybersecurity threats. A partial matrix emphasizing the top priority risk and the corresponding acceptability matrix are shown below in Figures 6 and 7, respectively. See Appendix 6 for the full risk matrix.

Hazard	Situation	Harm	Acceptability Risk	Severity	Controls	Verification	Residual Risk Occurrence	Acceptability
Flashing Images	GUI with video or moving images (gifs) that exceed recommended frame rate	Triggers seizure	3 3 <b>9</b>	Intolerable	No more than 3 flashes per second of any image or video	WCAG 2.2 SC 2.3.1 (PEAT Tool)	1 <b>4</b>	Caution

Figure 6. Device Risk Analysis - Partial (Top Priority Risk)

Probability	Unlikely	Remote	Possible	Probable
Severity	1	2	3	4
Catastrophic				
5				
Severe				
4				
Major				
3				
Minor				
2				
Negligible				
1				

Figure 7. Risk Acceptability Criteria Matrix

*Acceptability Criteria.* Risk acceptability falls into one of the following categories:

1. Category 1 (Green): Acceptable risk. Further risk control is not required but may be applied.
2. Category 2 (Yellow): Caution. Further risk control should be considered. If the risk cannot be reduced, a Benefit Risk Analysis may be used to justify the risk level, but may include multiple risks.
3. Category 3 (Red): Unacceptable risk. Further risk control must be considered. If reduction of risk is not possible, a Benefit Risk Analysis must be performed to justify the risk, or the feature (or product) must be removed from consideration.

As the hazard of flashing images had the highest risk and residual risk values (at 9 and 4, respectively), implementation and testing of this risk control was prioritized. The following section outlines the full analysis and testing results for this top priority hazard. Management should ensure remaining controls are implemented and tested prior to product release.

*Top Priority Hazard Analysis.* The identified hazardous situation is the moving of GUI elements at a higher than recommended frame rate, which could induce the corresponding harm of seizures. To mitigate this risk, we implemented the control that there should be no more than three flashes per second of any image or video, which comes from the software guideline WCAG 2.0, subsection 2.3. To verify that this control has been implemented into our front-end GUI prototype, we utilized the Photosensitive Epilepsy Analysis Tool (PEAT), developed by the University of Maryland Trace Center. Upon analyzing video capture of the prototype, PEAT generated a report, confirming compliance with WCAG 2.0 and successful risk control implementation (see Appendix 6).

### IV. Regulatory Strategy

*Route to Market.* The U.S. has been strategically identified as the location for our initial product launch, due to factors such as location of physician champions and stakeholders, information about established insurance plans, and regulatory requirements. This will require approval from the FDA; expectations and assumptions about this process are outlined in the following sections.

*FDA Regulatory Path.* Potential candidates for a predicate device included the DryTime for Potty Training (510(k) K962416), Hughes Bladder and Bowel Training System (K971442), and Smart Incontinence Management (SIM) System (K130951), however, upon closer review, there is not strong evidence for substantial equivalence. Specifically, they lack the predictive element achieved with a ML

algorithm, and/or have different intended users. As there are no existing products with similar enough intended use and technological characteristics to claim substantial equivalence, we do not anticipate qualifying for a 510(k) submission; rather, we expect to follow the De Novo pathway.

*Risk Classification and Product Code.* Without a relevant predicate device, the product will most likely initially be classified a Class III device; however, submission of a Reasonable Assurance of Safety and Effectiveness (RASE) form is expected to reclassify the device to a Class II. This classification is most appropriate for the DaySense as all foreseeable hazards could be reasonably contained with special controls and it does not provide critical support, yet the ML algorithm requires regulation beyond general controls. Additionally, the product code most applicable to the DaySense is KPN, as all “enuresis alarms” fall under KPN[20]. Due to the alert system and DayWatch, the DaySense could be considered an enuresis alarm device.

*Expected FDA Interactions.* Prior to the De Novo submission, a Pre-Sub meeting should be conducted with FDA to confirm the assumptions regarding regulatory pathway and risk classification, propose anticipated studies, and inquire about cybersecurity requirements. The De Novo submission should be completed and submitted to FDA as soon as possible afterwards and the submission number recorded.

## V. Development Plan

### Manufacturing Plan

During the initial development phase of the DaySense, we expect to produce 340 units per year for R&D, clinical trials, and testing. Once we reach the first 1-2 years of early sales and pilot deployment we plan for a 500 annual product volume. Through market entry into pee clinics and direct to patients, we expect a total of 14,650 units per year to obtain a 20% market share in each respective market. During later-stage expansion into the potty-training market, we would produce 48,100 units to maintain a 5% market share. The manufacturing methods for both the SenseBand and DayWatch follow a similar procedure. The PCB board and respective sensors and display will be created and assembled. The software for each module will be uploaded to the microprocessor and tested for quality purposes. The casing for the SenseBand and DayWatch will be injection molded using ABS plastic. The DayWatch silicone straps will be outsourced with generic materials, while the SenseBand strap will be made in-house using compression molding. The PCB and battery will be assembled inside the respective casing and the straps will be attached to complete the assembly.

The BOM seen in Tables 2 and 3 highlight the components used in our design. The total BOM using this material list and averaging costs would be \$50.25. Based on this BOM, we can extrapolate the cost per unit to be \$157.50.

Silicone Wristband	\$0.50-1.00
LED Display	\$3.00-6.00
BLE-enabled Microcontroller	\$4.00-8.00
Lithium-ion 200mAh battery	\$1.50-3.00
PCB Board	\$3.00-5.00
PCB Board Circuitry	\$1.00-2.00
Assembly & Manufacturing	\$2.00-4.00

Silicone Knee Band	\$0.50-1.00
BLE-enabled Microcontroller w/ SD Support	\$4.00-8.00
8 GB SD Card	\$3.00-5.00
MAX30102 Heart Rate Sensor	\$3.00-6.00
Grove 3-Axis Accelerometer	\$1.50-3.00
Lithium-ion 200mAh battery	\$1.50-3.00
PCB Board	\$3.00-5.00
PCB Board Circuitry	\$1.00-2.00
Assembly & Manufacturing	\$2.00-4.00

Tables 2 and 3. BOM for DayWatch (left) and SenseBand (right)

## **Cybersecurity Plan**

Since our device uses software, we would be required to perform appropriate cybersecurity measures. Our device does not contain any identifying or sensitive information and does not connect to any networks, meaning the risk related to software is not high. Appropriate encryption of the bluetooth communication and the physical case containing the microprocessors would be appropriate measures to ensure sufficient risk mitigation related to software.

## **Sustainability**

Throughout the design process, sustainability was kept in mind. We created a modular design that allows for components to be swapped as needed. This means if a battery or sensor is broken, it can be replaced without needing a whole new product. We also used rechargeable batteries in both the DayWatch and SenseBand to reduce waste. Through the NextDaySense takeback program we will reuse working components in returned damaged devices to promote recycling within our circular economy and reduce waste.

## **Monetization Plan**

Our initial monetization plan is to sell directly to pee clinics as a treatment tool as well as directly to patients' caregivers. While selling to pee clinics, we would be considered a primary procedure and would be reimbursed through either professional provider pathways, ICD-10 Dx of the National Center of Health Statistics for MD, PT, PA professional providers and CPT of AMA for MD office in-person/virtual visits and at home, or through the facility pathway, HCPCS of CMS Working Group for MD office in-person/virtual visits[21], [22], [23]. Selling direct to consumers, however, would not have coverage and would need to be paid out of pocket. When selling directly to consumers, we would use a physical distributor with a 45% markup to cover our costs. When selling to patients, we would only use an online distributor with only a 30% markup to cover costs while reducing prices for consumers. These would help our challenge of our COGS not being feasible with our BOM, allowing for a higher COGS.

Once we establish our product through pee clinics and direct to consumers as a treatment for diurnal enuresis, we plan on expanding into other avenues to create profit. This includes licensing our technologies to other companies and expanding into other markets, including potty-training and geriatric care. Through these markets we hope to greatly expand the business and create significantly more profit. Through this business plan, there are many strengths and weaknesses. We are able to address a large clinical need with our novel technology, with opportunities for market expansion and licensing. On the other hand, since we have novel technology, there is greater front end work to prove it works with a need for extensive data collection. Additionally, there would be a high price point for patients' families and limited revenue in the initial years of sales.

## **Path Forward**

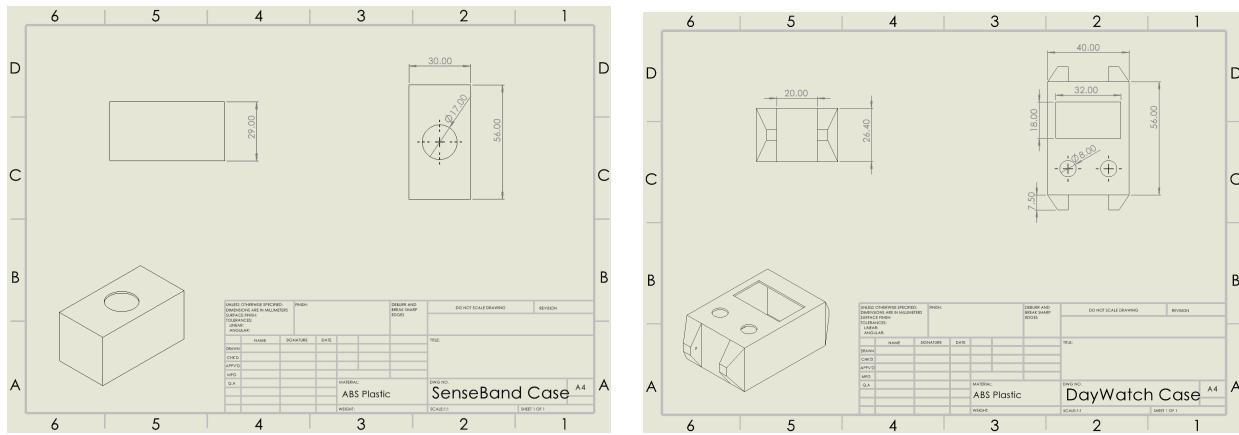
Considering the current gap in the market for a diurnal, predictive enuresis monitor that promotes behavioral change, DaySense has the opportunity to fill a large need. Due to DaySense's ability to fill this need and help millions of lives, we feel this product should be continued and invested in. There are, however, many gaps that would need to be filled before launching the product. In terms of the development, further design for manufacturability and system integrations will need to be made. Discussions with manufacturers to have a better idea of how much it would cost to manufacture the device would be valuable in further creating a viable business plan.

## Works Cited

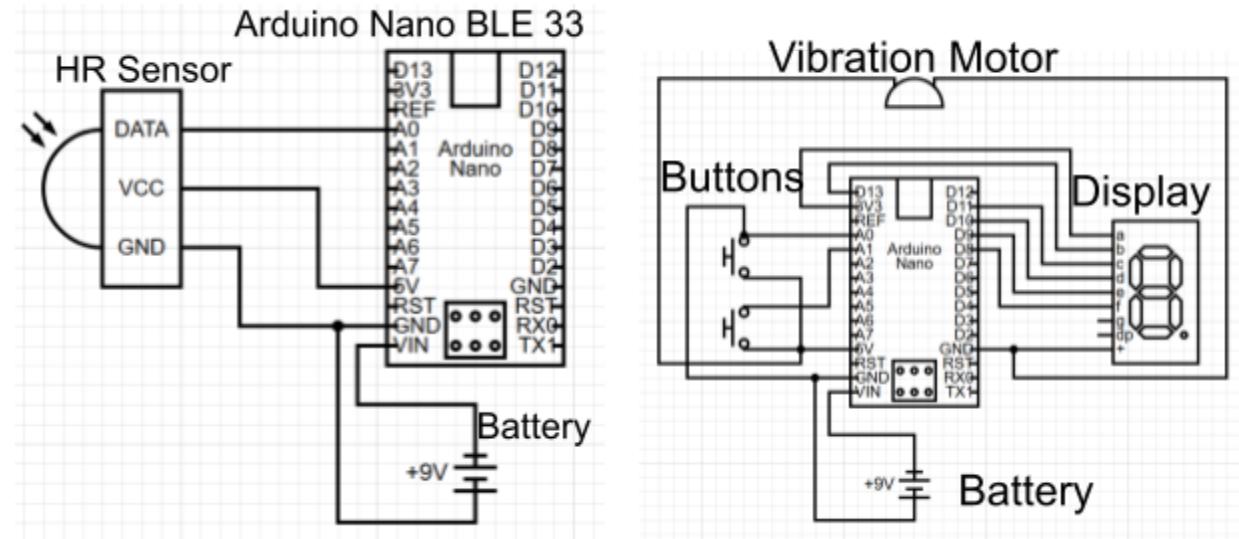
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## Appendix 1. Draft Device Master Record (DMR)



Engineering Specifications for the SenseBand (left) and DayWatch (right) cases



Schematics for the SenseBand (left) and DayWatch (right) circuits

## Appendix 2. Results of V&V Testing

### Traceability Matrix

*Prototype Documentation*

[DayWatch GUI Logic Flow](#)

[SenseBand-DayWatch Communication](#)

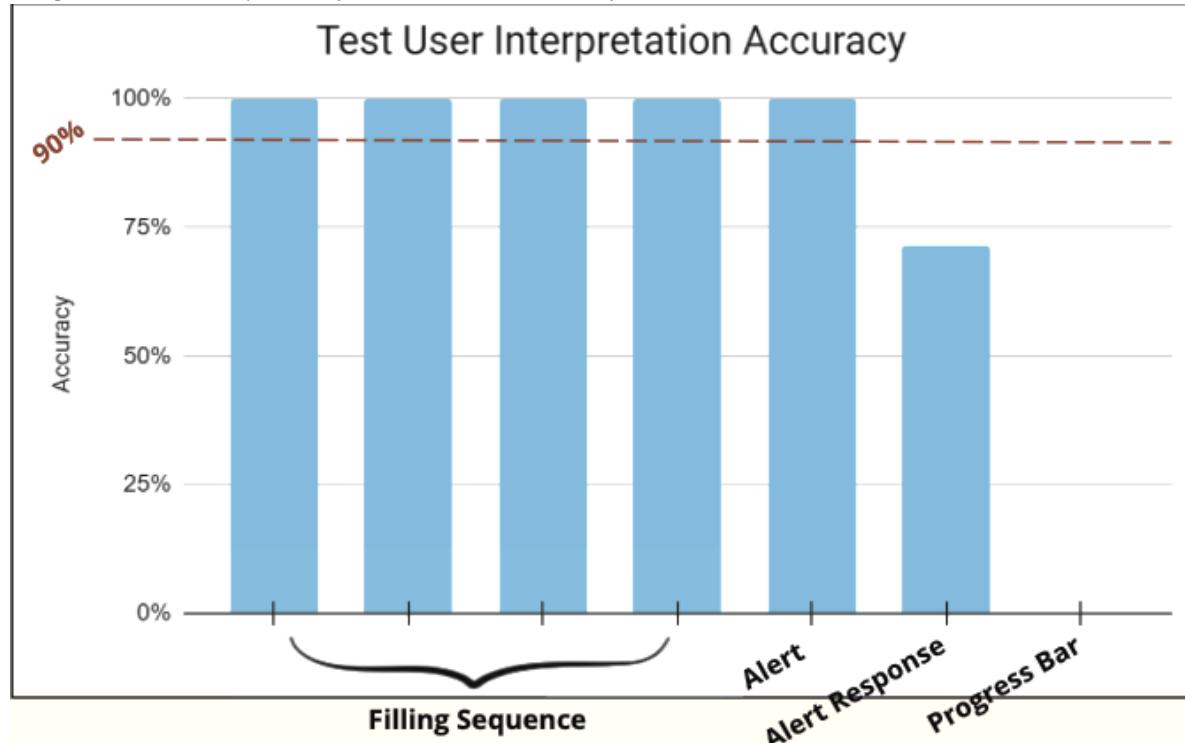
*Test Documentation*

Test Name	Supplemental Documents	Test Record(s)
<a href="#">TP00001 v2.0</a>	<a href="#">SS00001 v1.0</a> <a href="#">TP00001v2.0.SampleTrainingData.csv</a> <a href="#">TP00001v2.0.SampleTestData.csv</a> <a href="#">TP00001v2.0.DaySense-MLP pipeline.ipynb</a>	<a href="#">TR00001v2.0_1</a> <a href="#">TR00001v2.0_2</a> <a href="#">TR00001v2.0_3</a>
<a href="#">TP00002 v1.0</a>	<a href="#">ES00001v1.0</a>	<a href="#">TR00002v1.0_1</a> <a href="#">TR00002v1.0_2</a> <a href="#">TR00002v1.0_3</a> <a href="#">TR00002v1.0_4</a> <a href="#">TR00002v1.0_5</a>
<a href="#">TP00003 v1.0</a>	<a href="#">ES00001v1.0</a>	<a href="#">TR00003v1.0_1</a>
<a href="#">TP00004 v1.0</a>	<a href="#">SS00002v1.0</a> <a href="#">Usability Testing User Response Form 1.pdf</a> <a href="#">Usability Testing User Response Form 2.pdf</a>	<a href="#">TR00004v1.0_1</a> <a href="#">TR00004v1.0_2</a> <a href="#">TR00004v1.0_3</a> <a href="#">TR00004v1.0_4</a> <a href="#">TR00004v1.0_5</a> <a href="#">TR00004v1.0_6</a> <a href="#">TR00004v1.0_7</a>

*Verification Testing Results for the DaySense AI*

Subject	Accuracy	Specificity
1	83%	71%
2	100%	86%
3	88%	88%

*Average User Accuracy Rates for GUI Element Identification*



### Appendix 3. Itemized Budget Summary

#### DaySense 2024-2025 Budget Summary

Item	Cost	Purpose
Galvanic Skin Response Sensor	\$17.59	Test correlation between sweat and oncoming enuresis
Gyroscope	\$51.17	Test correlation between leg movement and oncoming enuresis
Push Buttons	\$9.26	Way for user to interact with DayWatch
TFT Display	\$11.39	Display alerts for user of oncoming enuresis
Arduino Nano 33 BLE	\$60.59	Microprocessor for SenseBand and DayWatch
SD Card Adaptor	\$13.69	Allow microSD card to be compatible with Arduino
SD Card	\$26.65	Store data from sensors while testing
Vibration Motor	\$8.08	Alert user of oncoming enuresis
Amazfit Band 7 Fitness Watch	\$34.99	Record heart rate continuously during testing
<b>Total</b>	<b>\$233.41</b>	

## Appendix 4. IP Landscape

### DaySense 2024-2025 IP Search

Product	Patent/Application #	Exp. Date	Claim Avoided for FTO	Explanation
GOGO Band	US-11430245-B2	8/30/2042	1. A system, comprising: one or more data processors; and a non-transitory computer-readable storage medium containing instructions which, when executed on the one or more data processors, cause the one or more data processors to perform operations including: receiving biometric data associated with a unique identifier, wherein the received biometric data is heart rate data, ambient temperature data, body temperature data, blood oxygenation data, skin conductivity data, blood pressure data, electrocardiogram data, electroencephalogram data, electromyographic data, respiration rate data, sleep quality data, depth of sleep data, restfulness data, heart rate variability data, or combinations thereof, and wherein the biometric data does not include a bladder measurement;	DaySense will focus on <b>accelerometer data with a combination of heart rate, leg proximity, and/or skin conductivity.</b>
GOGO Band	US-10905368-B2	2/2/2041	3. The system of claim 1, wherein the operations further include: receiving demographic information associated with the unique identifier, wherein the demographic information is indicative of a population of users; <b>selecting a baseline model from a set of potential baseline models using the received demographic information</b> , wherein the selected baseline model is trained using historical data collected over time from the population of users; and generating the urination prediction model using the baseline model.	DaySense will generate a model from user's own biometric data during a "training period"
GOGO Band	US-10685249-B2	6/16/2040	3. The bedwetting training method according to claim 1, wherein the bladder monitoring device comprises an ultrasound or photo optical sensor, and wherein the <b>volume of the bladder is calculated using the ultrasound or the photo optical sensor.</b>  5. The bedwetting training method according to claim 1, wherein determining the volume of the bladder based on the detected signal changes comprises: determining an initial volume of the bladder at a first time; calculating an amount of urine generated in the bladder per unit time based on the detected signal changes; <b>determining an amount of elapsed time since the first time multiplying the amount of urine generated per unit time by the amount of elapsed time to determine the volume of the bladder.</b>  6. The bedwetting training method according to claim 1, further comprising a <b>bedwetting sensor</b> that provides a signal representative of whether the patient wets the bed.	We will not be incorporating an ultrasound to predict urine volume in bladder  We will be utilizing machine learning to recognize patterns in movement data using <b>accelerometer as our primary mode of prediction</b> + additional biometrics (chosen from: heart rate, sweat amount, distance. between legs)  We do not have a bed wetting sensor - targeting daytime use
TAMAGOTCHI	US5966526	10/12/2019	4. The system of claim 1, wherein the operations further include: receiving demographic information associated with the unique identifier; <b>selecting a baseline model using the received demographic information</b> ; and initializing the urination prediction model using the baseline model.  5. The system of claim 1, wherein the operations further include: <b>selecting a baseline model using the biometric data</b> ; and initializing the urination prediction model using the baseline model.	GOGO band uses a prediction model based on demographic information. We will be using ML for each user by <b>implementing a "training period" using real data</b> from the user.  see above
Product	Patent #	Exp. Date	Claim Avoided for FTO	Explanation
Progress Pyramid	US20060172268A1	Abandoned	2. wherein the control unit is provided with calling means wherein the virtual creature makes a call in a <b>procedure of growing the virtual creature</b> ; wherein the inputting means is provided with a means for taking care of the virtual creature and a means for <b>disciplining the virtual creature</b> in response to the call from the virtual creature;  9. The system of claim 1, further comprising: a stop sign or a do not disturb sign; a plurality of craft tools; means for creating a contractual instrument which defines goals, values, rewards for exceeding expectations, <b>misbehavior, and consequences for misbehavior as agreed upon by both the caregiver and the child;</b>	DaySense's Eugene will not have any elements of growth or discipline. Eugene will reflect the status of the user but be represented by a virtual creature.  "Pyramid Progress" star chart implements elements of addressing misbehavior. DaySense will only reward desired outcomes. There will be no elements of discipline in the DaySense system.

## **Appendix 5. DaySense Non-Critical User Needs and Design Requirements**

User Need	Design Requirement
Solution is affordable for patients' families	Solution price is less than \$750
Solution can be easily set up by patients	Solution set-up takes less than 5 minutes of setup and requires less than 3 user steps

## Appendix 6. Risk Management Plan

### DaySense 2024-2025 Risk Management Plan

Line #	Hazard	Situation	Harm	Severity	Occurrence	Risk	Acceptability	Controls	Verification	Residual Risk Occurrence	Acceptability	
1	Electricity	Uninsulated wiring or connection points come in contact with water/liquid	Device shocks user	2	4	8	Intolerable	Insulated connection points, methods for insulating wiring	IEC 60601 testing and verification (wire wrap test, leakage current test)	1	3	Caution
2	Heat	Device overheats from continued use	Second degree burn	3	1	3	Caution	Thermal protection, plastic layer, air conditioner	IEC 60601 testing and verification (maximum temperature test)	1	3	Caution
3	Heat	Device overheats from continued use	First degree burn	2	2	4	Caution	Thermal protection, plastic layer, air conditioner	IEC 60601 testing and verification (maximum temperature test)	1	2	Acceptable
4	Alert failure	Device alerts to use restroom when not needed	User goes to restroom w/out needing to	1	4	4	Caution	Training period allows machine learning to better predict need to use restroom	Usability testing, track successful and unsuccessful notifications and should see decrease in false alarms over time	2	2	Acceptable
5	Alert failure	Device does not alert when needed to use restroom	User experiences wetting accident	2	3	6	Caution	Increased sensitivity for potential need for restroom, alert every X hours that they should use the restroom regardless of activity	Usability testing, not using restroom for X amount of time and ensuring the alert notifies user	1	2	Caution
6	Broken casing	Casing on device breaks from continued use or impact	Piece gets stuck in user	3	2	6	Intolerable	Casing with high mechanical properties, cushioning around device	IEC 60601 testing and verification (drop testing)	1	3	Caution
7	Broken casing	Casing on device breaks from continued use or impact	User has a deep cut	3	2	6	Intolerable	Casing with high mechanical properties, cushioning around device	IEC 60601 testing and verification (drop testing)	1	3	Caution
8	Broken casing	Casing on device breaks from continued use or impact	User has a minor cut	2	2	4	Caution	Casing with high mechanical properties, cushioning around device	IEC 60601 testing and verification (drop testing)	1	2	Acceptable
9	Flashing Images	GUI with video or moving images (gifs) that exceed recommended frame rate	Triggers seizure	3	3	9	Intolerable	No more than 3 flashes per second of any image or video	WCAG 2.2 SC 2.3.1 (PEAT Tool)	1	4	Caution
10	Cybersecurity Threats	Hackers breach the software of device	Patient Information is breached	2	1	2	Acceptable	Cybersecurity protocols to protect user information	IEC 11073	1	2	Acceptable

### *Device Risk Analysis - Full Matrix\**

*\*Note: Matrix items are organized by hazard (not priority).*

PEAT Test Results											
Results of analysis for compliance with Guideline 2.3 of the Web Content Accessibility Guidelines (WCAG) 2.0											
Video clip file name: Untitled designConverted.avi Frame rate: 25 fps Length of material: 000:56.22 Analyzed on: Monday, April 14, 2025 -- 12:46 AM											
Result status: Passed Luminance flash failures: 0 frames Red flash failures: 0 frames Extended flash warnings: 0 frames											

*Test Results Report generated by PEAT during Risk Control Verification.*