AI Sleeper Assisstant

Group 1

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Clinical Unmet Needs

- **Commercial sleep aids (e.g., sleeping pills, melatonin patches, medications, gummies) may cause addiction, have side effects, and are difficult to obtain. CES devices are expensive, bulky, and complex to operate, making long-term use impractical.**
- **Seeing a doctor involves high costs, complicated scheduling, and lacks immediacy.**
- **Sleep products like white noise machines and breathing lights show limited effectiveness.**
- **Consumers seek sleep solutions that are *safe, simple, instant, effective, suitable for long-term use*, and *personalized*.**

Product Introduction

Product Description:

AI-Sleeper Assistant utilizes Cranial Electrotherapy Stimulation (CES) technology, delivering low-intensity electrical currents through adhesive patches to the temple area. This modulates the brainwave frequency and power, enhancing alpha (α) and delta (δ) wave activity to promote relaxation and sleep. Equipped with a Bluetooth wireless transmission module and AI algorithms, the device dynamically adjusts stimulation based on real-time brainwave data.

Product Composition

- **Adhesive Patch Module**: Soft and skin-friendly, approximately 10 mm in diameter. Comfortable, non-allergenic, and highly reusable.
- **CES Microcurrent Stimulation Module**: Simulates brainwave rhythms and delivers safe electrical currents to stabilize neural activity.
- **Built-in Lithium Battery**: Supports magnetic charging. Lasts over one week per charge, typically charged once a month.
- **Wireless Transmission Module**: Uses Bluetooth to transmit brainwave and device parameter data in real time to the mobile app.
- **Mobile App**: Displays sleep information, adjusts current parameters, and records usage history.
- **AI Smart Algorithm**: Automatically adjusts stimulation intensity and frequency based on sleep stages to improve sleep onset and reduce disturbances.

Product Introduction

How to Use the AI Sleeper Assistant ?

Recommended Usage Time

Use at night before sleep, ideally while lying calmly in bed.

Operating Procedure

1. Clean both temple areas and apply the electrode patches.
2. Power on the device and use the mobile app to select a stimulation mode and set the duration (default: 30 minutes).
3. Begin sleeping — the device will automatically adjust current levels and monitor brainwaves in real time.
4. After the session, the app provides a detailed sleep report for user reference.
5. After each use, remove the patches, wipe them clean, and store them properly.

Suggested Usage Frequency

Use once daily. Continuous use for 1–2 weeks may yield noticeable effects. The device can also serve as a long-term, non-pharmaceutical sleep aid.

Product Use

Intended Use

The device uses **microcurrent brain stimulation** and an **AI-driven brainwave analysis system** to help users relax their nervous system, improve sleep onset efficiency, and enhance overall sleep quality. It records brainwave data in real time and provides personalized sleep reports via a mobile app, supporting individualized sleep health management.

Indications

- Individuals with sleep disorders such as difficulty falling asleep, light sleep, or frequent nighttime awakenings
- Users who have tried sleeping pills or melatonin without success, or prefer non-pharmaceutical solutions
- Individuals interested in self-monitoring and adjusting their sleep-related behaviors

Product Specialities

This product is a high-efficiency sleep induction system that integrates **AI sleep analysis** with **brainwave modulation technology**. Designed specifically for individuals with insomnia, it offers a complete, medical-grade sleep solution that's safe and convenient for home use—from identifying root causes to delivering effective improvement.

- **AI sleep analysis with PSG-level accuracy (90%)** to pinpoint the underlying causes of insomnia
- **Six key sleep indicators** with clear, easy-to-understand feedback
- **Automatic and precise brainwave modulation**, clinically tested and scientifically validated with 90% effectiveness
- Helps users reach **deep sleep within 5 minutes**, significantly improving sleep quality.

Medical Device Regulations

Safety Verification Standards

- **IEC 60601-1:2005/AMD2:2020** — General safety and essential performance requirements for medical electrical equipment
- **IEC 60601-1-2** — Electromagnetic compatibility (EMC) testing
- **IEC 60601-1-11** — Safety requirements for medical equipment intended for home use
- **IEC 60601-2-26** — Specific performance and safety standards for electroencephalographs (EEG)
- **IEC 62304:2006+AMD1:2015** — Software life cycle processes for medical devices

Functional Testing Standards

- **IEC 62366-1** — Usability engineering design standard for medical devices

Preclinical Performance Testing

- **TFDA Guideline** — Reference document on real-world data and evidence supporting medical device decision-making (Taiwan Food and Drug Administration)

Risk Control

Contraindications

- **Pregnant women** (the effects of electrical stimulation on the fetus have not been established)
- **Individuals with epilepsy or implanted brain devices**
- **Users with infections or wounds in the temple area**
- **Children under 12 years old** (due to immature brain development)

Function / Mechanism	Potential Hazard	Source of Hazard	Likelihood	Severity	Control Measures
Electrical Stimulation	Dizziness, nausea	Individual differences in current tolerance	Low	Low	Provide adjustable intensity settings and pause function to prevent overstimulation
Patch Contact	Skin rash or allergy	Individual sensitivity, patch material	Low	Low	Use hypoallergenic materials; recommend daily patch replacement
Wireless Transmission	User data leakage	Unencrypted transmission	Very Low	Medium	Data encryption and anonymization

Market Size Analysis

Business Model

Competitor Analysis

Market Value

Market Size

Business Model

Business Model

This product is a **consumer-grade medical device** adopting a **hybrid B2C + B2B2C model**.
It initially targets the **self-pay personal market (B2C)** while partnering with selected clinics (B2B2C) to build trust and brand influence.

Sales Channels & Usage Scenarios

- **Online Channels**:
  Direct-to-consumer e-commerce and third-party platforms (e.g., momo, PChome, Shopee Health Pavilion)
- **Physical Partnerships**:
  Sales collaborations with neurology/psychiatry clinics and sleep disorder centers
- **Promotional Exhibitions**:
  Trial promotions at health expos, sleep society annual meetings, and medical forums

Business Model

Revenue Sources

- **Main device sales**: One-time purchase
- **AI sleep analysis app**: Monthly or annual subscription
- **Consumable patch modules**: Sold via subscription or in bulk packs

Pricing Strategy

- **Main device**: NT$30,000–40,000 (priced lower than comparable CES devices)
- **Patch consumables**:
    - Subscription: NT$300–500/month
    - Bulk pack: NT$150 for 10 patches
- **App advanced analytics plan**:
- NT$99/month, NT$960/year

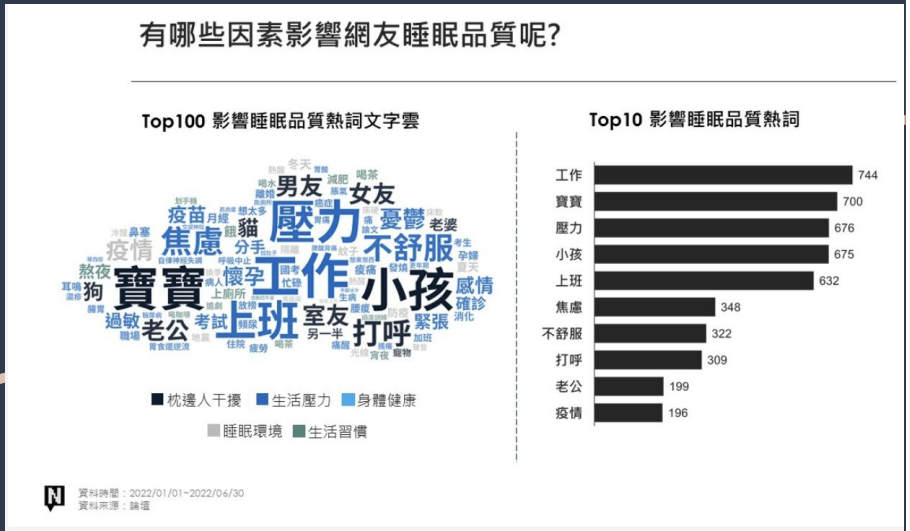
Market Size

Market Hierarchy		Estimated User Population	Estimated Market Value
TAM	Total population with insomnia or sleep issues	2.7 million people	NT$1.1 trillion (theoretical)
SAM	Medium-to-high willingness to try tech-based sleep aids	540,000 people	NT$220 billion
SOM	First-stage target users (early adopters)	11,000–27,000 people	NT$440 million – NT$1.1 billion

Competitor Analysis

Brand / Product	Core Technology	Price Range (NT$)	Advantages	Disadvantages
Fisher Wallace Stimulator (USA)	CES	20,000–30,000	FDA Class II approved, clinically proven effectiveness	High price, requires prescription, mainly sold within the U.S.
Muse S Headband (Canada)	EEG + Guided Meditation	12,000–18,000	Comfortable headband, detailed data, integrated meditation training	No active electrical stimulation, better for relaxation than insomnia
Philips SmartSleep (Netherlands)	Sound induction + sleep tracking	15,000–22,000	Trusted brand, low stimulation risk, clinical support	Suitable only for mild insomnia, lacks real-time brainwave modulation
Dreem 2 Headband (France)	EEG + White noise stimulation	18,000–25,000	PSG-grade brainwave analysis, sleep-inducing audio features	Heavier, relatively expensive, requires fixed sleeping posture

Market Size



Sleep Technology Market Overview

- Global market size in 2023: approximately **USD 18.4 billion**
- Projected compound annual growth rate (CAGR): **17.8%**
- Estimated revenue by 2034: over **USD 108.6 billion**

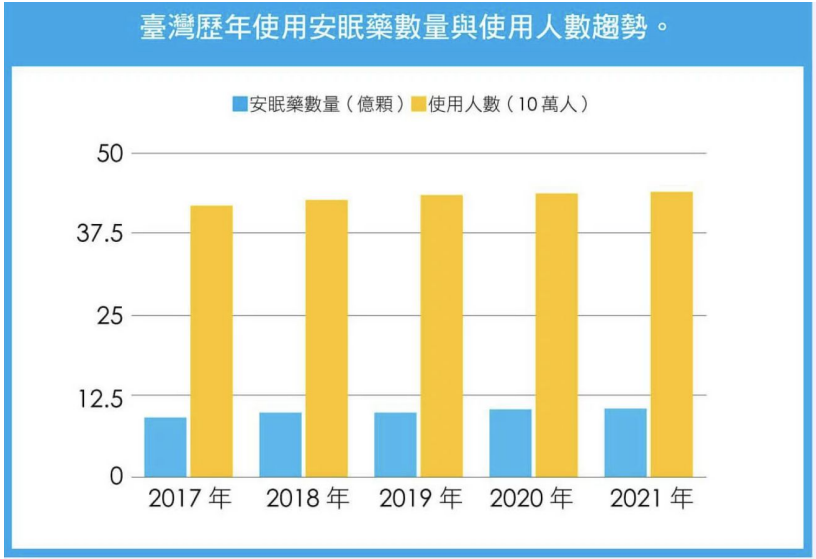
Growth Drivers

- Continuous advancement in sleep technology devices
- Aging global population
- Increasing noise pollution
- Rising prevalence of sleep disorders

Market Size

Sleep Disorder Prevalence

- Global insomnia prevalence: approximately **10–30%**, with some regions reaching as high as **50%**
- Prevalence of sleep disorders among **Taiwanese adults**: **23.5%**



Thank You for Listening!!!