# White Paper

# Defining Four Categories of Wearable Technology for Sleep Disorders

**Global Policy and Regulation Committee, ISSTA (www.isstasleep.org )**

## Executive Summary

The rapid evolution of wearable technologies presents unprecedented opportunities for advancing sleep medicine. Yet, a critical gap remains between the pace of innovation in the technology industry and the requirements of the medical field for accuracy, reliability, and integration into clinical care. This white paper proposes a framework of four categories of wearable technology for sleep disorders, offering a path toward standardization, clinical acceptance, and interdisciplinary collaboration.

## Introduction

Sleep disorders such as obstructive sleep apnea (OSA), insomnia, and restless legs syndrome (RLS) affect hundreds of millions worldwide. Despite their prevalence, diagnostic and follow-up care remain limited by access to specialized sleep labs and long waiting times. Wearable technologies, when properly validated and standardized, can transform early detection, monitoring, and long-term management.

The International Sleep Science and Technology Association (ISSTA), through its Global Policy and Regulation Committee, has developed a four-category framework for wearable technologies in sleep medicine. This categorization balances clinical needs, technological capabilities, and regulatory pathways, and aims to foster alignment between the healthcare and technology sectors.

## Four Categories of Wearable Technology for Sleep Disorders

**Germany**: Luisenstrasse 55, 10117 Berlin
TEL: +49-30-4505-13013

**USA**: Medical Campus, Sam Houston State University
925 City Central Avenue, Conroe, TX 77304
secretary@isstasleep.org TEL: +1-936-202-5226

## 1. Pre-Screening & Educational Wearables (LLM-Integrated, Home-Based)

Empower individuals to learn about their sleep health and recognize potential risks.
- Users: General public, wellness coaches, and non-specialist healthcare providers.
- Features: Motion sensors, heart rate, oxygen saturation, AI-driven sleep education.
- Standards Needed: Accuracy thresholds, transparency on limitations, interoperability with clinical systems.

## 2. Wearable Home Sleep Testing (HST) for Family Doctors

Bridge primary care and sleep specialists by enabling screening and partial diagnosis.
- Users: Family doctors, community clinics.
- Features: Portable EEG, $SpO_2$ sensors, airflow sensors, AI cloud algorithms.
- Standards Needed: FDA/CE validation against PSG, defined benchmarks, referral protocols.

## 3. Wearables for Treatment Follow-Up by Sleep Specialists

Provide longitudinal data during treatment to optimize interventions.
- Users: Sleep specialists, multidisciplinary teams.
- Features: CPAP adherence monitoring, EEG sleep stage analysis, AI alerts.
- Standards Needed: EMR integration, GDPR/HIPAA compliance, calibration intervals.

## 4. Long-Term Monitoring by Family Doctors and Families

Extend care beyond the clinic for sustainable, community-based sleep health.
- Users: Family doctors, caregivers, patients' families.
- Features: Simplified dashboards, predictive analytics, alerts to doctors.
- Standards Needed: User-friendly visualization, escalation pathways, multilingual access.

**Germany**: Luisenstrasse 55, 10117 Berlin
TEL: +49-30-4505-13013

**USA**: Medical Campus, Sam Houston State University
925 City Central Avenue, Conroe, TX 77304
secretary@isstasleep.org TEL: +1-936-202-5226

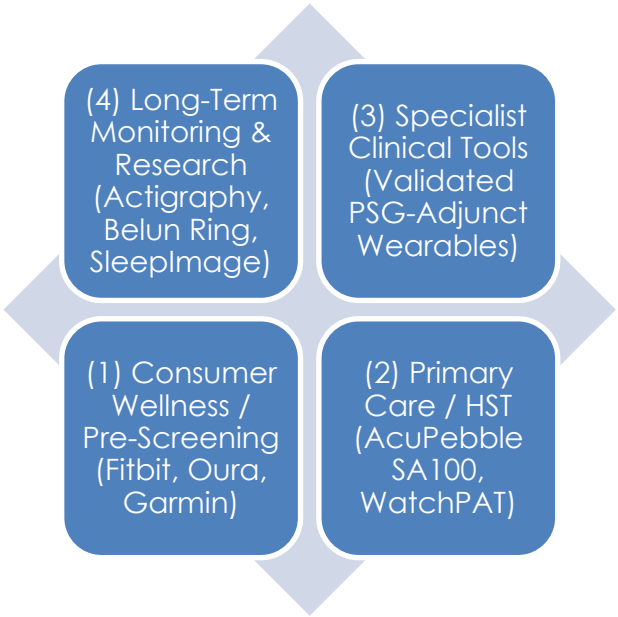
## Bridging the Gap: From Technology to Clinical Acceptance

To ensure wearable technologies are trusted by medical doctors, ISSTA proposes the following roadmap:

1. Validation Standards: Minimum technical benchmarks verified against PSG.
2. Interoperability: Integration with EMR systems.
3. Regulatory Alignment: Harmonizing FDA, CE, and Asian pathways.
4. Education & Training: Continuing education for doctors.
5. Collaborative Ecosystem: Joint ventures between universities, hospitals, and tech companies.

## Figures & Diagrams

### Figure 1. Four Categories of Wearable Technology (Quadrant Diagram)




### Figure 2. Clinical Workflow Integration of Wearables (Flowchart)

Integration path: Consumer → Primary Care → Specialist → Long-Term Monitoring

Source: ISSTA proposal for bridging wellness to clinical acceptance.

**Germany:** Luisenstrasse 55, 10117 Berlin
TEL: +49-30-4505-13013

**USA:** Medical Campus, Sam Houston State University
925 City Central Avenue, Conroe, TX 77304
secretary@isstasleep.org TEL: +1-936-202-5226

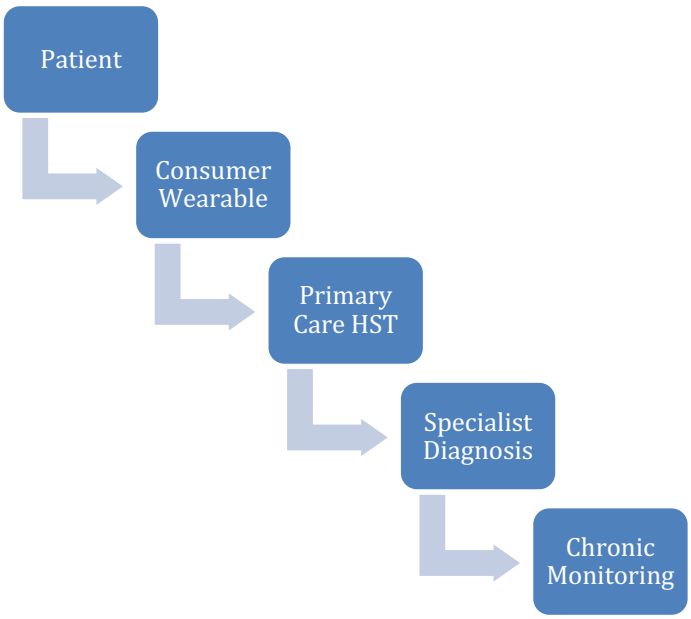
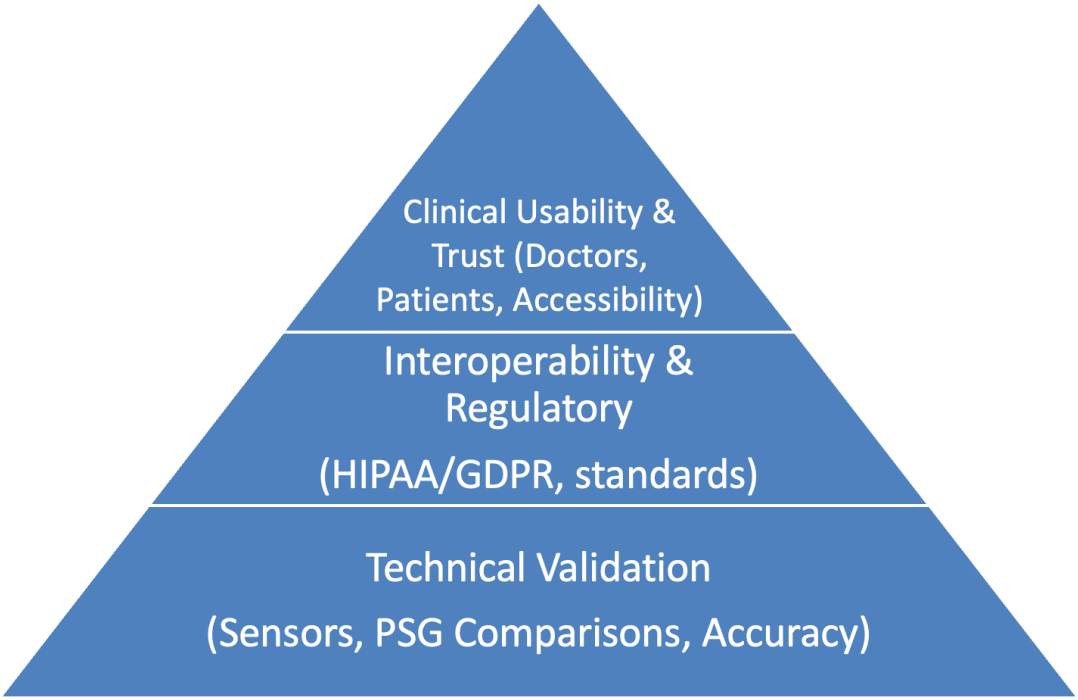



Figure 3. Standardization Framework (Pyramid Diagram)

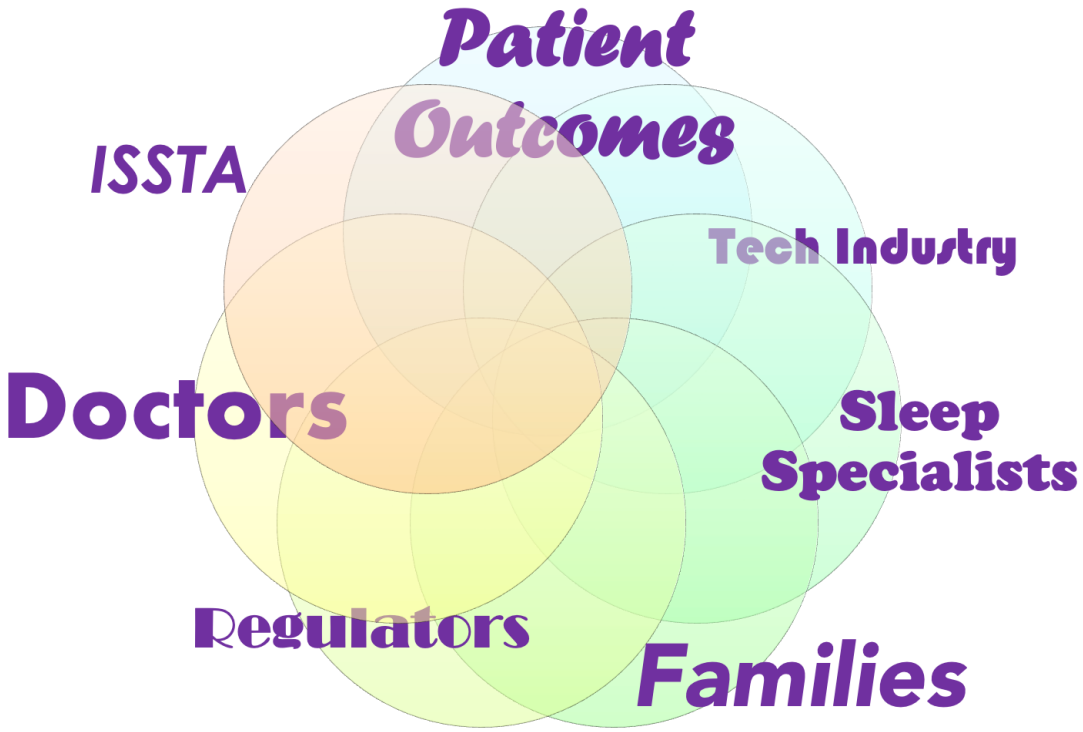



**Germany**: Luisenstrasse 55, 10117 Berlin
TEL: +49-30-4505-13013

**USA**: Medical Campus, Sam Houston State University
925 City Central Avenue, Conroe, TX 77304
secretary@isstasleep.org TEL: +1-936-202-5226

Figure 4. Stakeholder Ecosystem Map (Circular Diagram)

Centering on Patient Outcomes; ensuring doctor–tech–policy collaboration.




## References

1. Chiang AA, Canapari C, Goldstein C and Baron K (2026) Editorial: The promise of sleep technology. Front. Neurosci. 20:1849903. doi:10.3389/fnins.2026.1849903.

2. Wu et al. Quantitative detection of sleep apnea in adults using inertial measurement unit embedded in wristwatch wearable devices. IEEE J Biomed Health Inform. 2021.

3. Sanchez-Gomez J, Pramono RXA, Imtiaz SA, Rodriguez-Villegas E, Morales AV. Validation of a Wearable Medical Device for Automatic Diagnosis of OSA against Standard PSG. J Clin Med. 2024;13(571).

4. Moreno-Pino F, Porras-Segovia A, López-Esteban P, et al. Validation of Fitbit Charge 2 and Fitbit Alta HR against polysomnography in adults with OSA. J Clin Sleep Med. 2019;15(11):1645–1653.

5. de Zambotti M, Goldstein C, Cook J, et al. State of the science and recommendations for using wearable technology in sleep and circadian research. Sleep. 2024;47(4):zsad325.

6. Kwon Y, Lim JS, Park H. Consumer sleep technology for the screening of obstructive sleep apnea and snoring: systematic review protocol. Syst Rev. 2022.

7. Li Y, et al. Scanning of obstructive sleep apnea syndrome using smartwatch: A comparison with polysomnography. J Clin Sleep Med. 2023.

8. Zhang X, et al. Sleep apnea screening based on PPG data from wearable bracelets using information-based similarity approach. Comput Biol Med. 2022.

9. Lee CH, et al. Comparative study of a wearable intelligent sleep monitor and polysomnography for OSA diagnosis. Nat Sci Sleep. 2022.

10. de Zambotti M, et al. A validation of six wearable devices for estimating sleep, heart rate, and heart rate variability in healthy adults. Sensors. 2021.

11. American Academy of Sleep Medicine (AASM). Clinical practice guideline for the use of actigraphy in the evaluation of sleep and circadian rhythms. J Clin Sleep Med. 2018.