PREPARED FOR CLINICAL REVIEW

NuCalm® Clinical Due Diligence

Everything a clinical reviewer needs to evaluate NuCalm, in one place: what it is, how it works, how safe it is, the evidence behind it, how data is handled, and what it costs.

NuCalm at a glance

- Software-only app for iPhone, iPad, and Android. Uses your own headphones, an eye mask, and a speaker for the sleep products.
- 8 products across 7 states of mind. Pick one and press play.
- Two U.S. patents (2015 and 2021).
- NuCalm has surpassed 2,500,000,000 total minutes played worldwide (equal to 4,756 years) as of 2026.
- Used in over 100 countries, with zero reported adverse events.
- No recalls, litigation, or enforcement actions, past or current.

1. The product users receive.

The intended function, user population, instructions, validation, device status, user risks, and product warranty.

ANSWER Users get the NuCalm mobile app, a software-only subscription for iPhone, iPad, and Android. NuCalm is patented neuroacoustic technology: layers of math, physics, and audio built to safely and precisely guide brain wave activity toward a target state through the frequency following response. It plays through the user's own headphones, in-ear buds, or a speaker for the sleep products. Pick a state of mind, press play. The NuCalm app features 8 unique products across 7 states of mind:

Product	Brain wave frequencies	Equipment and position	Length
DeepestSleep	delta (4Hz - 0.5Hz)	Speaker on the nightstand, all night	8 or 10 hrs
DeepestSleep+	delta (4Hz - 0.5Hz)	Speaker on the nightstand, all night	8 or 10 hrs
Rescue	alpha & theta (12Hz - 4Hz)	Headphones and eye mask, lying down	20–120 min
PowerNap	alpha & theta (12Hz - 4Hz)	Headphones and eye mask, lying down	20 min
FlowState	alpha (12Hz - 7.83Hz)	Headphones and eye mask, lying down	10–40 min
Focus	beta (15Hz - 20Hz)	Headphones, use while working / studying	15–60 min
Priming	gamma (40Hz)	Headphones, use during activity	7–16 min
Ignite	gamma (39Hz - 41Hz)	Headphones, use during activity	13–16 min

The app also includes the **Stress Test,** a third-party voice analysis feature. It analyzes ~10,000 biometric data points in 35 seconds of natural speech, the specific nervous system and vagus nerve biometrics, out of ~1 million data points in the full data set. It returns a coherence score from 0 to 100.

Intended function and user population

NuCalm is patented neuroacoustic audio technology intended for nervous system regulation, general wellness, stress management, sleep support, focus, and elevated energy on demand. It is not intended to diagnose, treat, cure, or prevent any disease or medical condition.

The intended users are people who want relief from stress, better sleep, and more focus, from everyday users to elite performers. Brain waves are rhythmic patterns of electrical activity in the brain, measured in Hz, running from the slowest to the fastest: delta > theta > alpha > beta > gamma. Each NuCalm product is designed around its own range, from delta (4Hz - 0.5Hz) for *DeepestSleep* to gamma (39Hz - 41Hz) for *Ignite*. NuCalm is the world's only patented solution for stress.

For amateur and professional athletes, the main uses are nervous system regulation, rest and recovery between training and competition, sleep during travel, and pre-competition readiness.

Instructions for use

1. Set the phone to Do Not Disturb, select the state of mind you want, then press Start.
2. For *Rescue*, *PowerNap*, and *FlowState*: lie down (best), recline, or sit only if there's no other option. Eye mask on, headphones on. An eye mask is required.
3. For *DeepestSleep* and *DeepestSleep+*: connect to an external speaker.
4. Take a break from *Focus* after 60 minutes.
5. Stop *Ignite* or *Priming* if you feel over-caffeinated or agitated.
6. Never use NuCalm while driving or operating machinery.
7. Download programs ahead of time (about 1GB each) so playback isn't interrupted.
8. Step-by-step guides for every state of mind: www.NuCalm.com/how-to-use

Validation

Published validation studies with independent, objective academicians, scientists, and doctors used physiological measures: EEG, QEEG, respiratory sinus arrhythmia, heart rate variability (HRV), skin conductance (GSR), heart rate, respiration, FMRI, and pulse oximetry. Please review some of the studies here: NuCalm Neuroscience

The Stress Test runs on a third-party voice analysis platform developed by Inner Voice.

Device status

Today's NuCalm mobile app is sold as a general wellness product, not a medical device. NuCalm was an FDA-cleared Class III medical device from 2009–2021, cleared for anxiety, depression, and insomnia. That was the clinical device, not today's app. Health Canada Approved (2009–2021) · NSF Certified for Sport (2009–2021; run by NSF International) · U.S. Military Approved (since 2013). NuCalm moved from the clinical device to a mobile app in November 2021. The method of action has always been the neuroacoustic software. After 12 years of constant innovation, we strengthened the neuroacoustic software to a place where we no longer needed biochemistry support. Now, it's just the software.

User risks

NuCalm is non-invasive, drug-free neuroacoustic software delivered through a mobile app. There are no pills and no side effects. NuCalm has surpassed 2,500,000,000 total minutes played worldwide (equal to 4,756 years) as of 2026. Across over 100 countries, there have been zero reported adverse events. A few things to pay attention to:

- Deep relaxation using *Rescue*, *PowerNap*, or *FlowState*. Never use while driving, or operating machinery.
- Feeling too energized to sleep if *Rescue* or *PowerNap* is used within 3 hours of bedtime.
- Feeling over-stimulated or agitated listening to *Ignite* or *Priming* (gamma: 40Hz for *Priming*, 39Hz - 41Hz for *Ignite*).
- Hearing: listen at a comfortable volume using headphones or in-ear buds.

Product warranty

NuCalm doesn't offer a product warranty or refunds. It's a monthly, annual, 5-year, or lifetime subscription, and can be cancelled at any time.

Safety record: no reported adverse events, recalls, litigation, or enforcement actions.

ANSWER

Item	Status
Adverse events	None reported
Warnings	Not for use while driving or operating machinery
Recalls	None, past or current
Litigation	None, past or current
Enforcement actions (FDA, FTC, state AGs)	None, past or current
Complaints and safety signals	None

The evidence, including full studies.

ANSWER All studies are published in full on the NuCalm research library. Each study page carries the complete text and a download of the original PDF, not just an abstract. The Dr. Wiles 2022 research summary gathers nine studies in one document.

Regulatory classification and status.

ANSWER

- Current NuCalm mobile app: general wellness neuroacoustic software
- Historical: NuCalm was an FDA-cleared Class III medical device from 2009–2021, cleared for anxiety, depression, and insomnia.
- Health Canada Approved (2009–2021)
- NSF Certified for Sport (2009–2021; run by NSF International)

- U.S. Military Approved (since 2013). NuCalm is currently a "Sole Source" provider to the Federal Government and Department of War.
- Patents: U.S. Patent No. 9,079,030, issued July 14, 2015: "Systems and methods for balancing and maintaining the health of the human autonomic nervous system."
- U.S. Patent No. 11,090,459, issued August 17, 2021: "Methods and devices for applying dynamic, non-linear oscillations and vibrations [to elicit a physiological state change in humans]."
- FDA clearance: K090052. NuCalm ended its FDA clearance in 2021 when it moved to a mobile app. Today's app isn't a medical device and no longer falls under FDA device regulation. The technology has also advanced beyond the earlier four-component system.

How data is collected, retained, and secured.

ANSWER

- Collected: name, email, billing information, usage data, IP address, device type, browser type, and app usage analytics.
- Use: providing and improving the service, processing transactions, communication, legal compliance, and aggregated research and analytics.
- Sharing: NuCalm does not sell personal information. It has never sold any customer data. NuCalm has been used in over 2,700,000 surgical procedures, and it is used across the U.S. Military, the FBI, public safety, the FedEx pilots' union, and professional sports. The company has never had a data breach, nor has any data ever been compromised. The company may share anonymized aggregated data with service providers, such as the FBI Hostage Rescue Team, or the VA upon request.
- Security: reasonable administrative, technical, and physical safeguards.
- User rights: access, correction, deletion, or restriction, depending on location, via support@nucalm.com.
- Stress Test recordings: not stored. The third-party vendor analyzes each recording and deletes it immediately after analysis.
- Organization access: no organization can see an individual user's data.

Promotional materials.

ANSWER

- Website: nucalm.com, How it works, The science, Studies
- Video: the *Rescue* explainer and How to Use NuCalm playlist on YouTube
- Video about NuCalm and sports: How NuCalm is Revolutionizing Sports Recovery and Performance
- Book: A New Calm (2016), by Michael Galitzer, M.D., and Larry Trivieri Jr., Foreword by Tony Robbins, Preface by Brother Craig Marshall, with a full PDF on the studies page
- Testimonials page
- Social: Instagram, Facebook, X, YouTube, LinkedIn

2. The problem NuCalm solves.

The current state of the art and known alternatives.

ANSWER

NuCalm addresses recovery: people need their nervous system to shift out of high-stress mode and into rest and repair, on demand, without drugs. Modern life stacks demanding work, travel across time zones, late nights, short sleep, and constant pressure from bosses, colleagues, families, communities, and themselves. For athletes, add hard training, competition, and constant travel. Each of these keeps the sympathetic (fight-or-flight) branch of the autonomic nervous system switched on, which cuts into sleep and recovery and challenges optimal performance.

Category	Examples	Limits
Sleep medication and supplements	Prescription sleep aids, melatonin, OTC antihistamines	Next-day grogginess, dependence risk, and supplement-contamination concerns under drug testing
Meditation and breathwork apps	Calm, Headspace, Open	Calm offers music and bedtime stories. Headspace and breathwork depend on practice and skill. Results vary by user and by stress response. (As of October 2026.)
Wearables and trackers	WHOOP, Oura	Measure sleep and HRV but don't change them
Wearable neurostimulation	Vibration and vagus-nerve devices	Extra hardware to wear and charge.
Recovery modalities	Cold tubs, compression, float tanks, massage	Facility-bound, time-heavy, hard to use on the road

How NuCalm advances the state of the art.

ANSWER

- No skill required. Pick a state of mind and press play. No practice and no experience needed.
- Drug-free. There are no pills and no side effects, which removes the contamination risk that supplements carry.
- Patented mechanism of action. The neuroacoustic software is designed to safely and precisely guide brain wave activity toward recovery states, protected by two U.S. patents. 36 years of patented neuroscience. NuCalm began in 1990.
- Portable. It runs on the user's own phone and headphones, so it works at home, at work, on the plane, in the hotel, and in the locker room.
- One app, 8 products, every aspect of daily life. Sleep, daytime recovery, focus, pre-performance readiness, and elevated energy.

The expected user benefit.

ANSWER

- A balanced nervous system. NuCalm is patented and clinically proven to balance the nervous system.
- Designed for a faster, more predictable shift into recovery after work, training, and travel.
- Deep restorative sleep all night long, at home or on the road.
- A short, structured reset before meetings, presentations, or competition.
- A drug-free alternative to sleep aids and relaxation supplements.
- Used by 79 professional sports teams since 2011.

How users measure success.

ANSWER

1. Stress Test coherence score before and after a *Rescue* session, to show the impact on nervous system regulation and NuCalm's cumulative improvement. Bands: 0–50 high stress, low coherence · 51–60 · 61–75 · 76–85 · 86–100 low stress, high coherence.
2. HRV and resting heart rate from the user's own wearable devices.
3. Sleep metrics: time to fall asleep, total sleep, sleep quality, sleep efficiency, deep sleep, REM sleep, and wakeups, from a wearable or sleep log.
4. Self-reported readiness, soreness, and mood on a daily 1–10 scale.
5. Consistency and streaks: sessions per week, logged in the app.

Competitors, and why NuCalm is different.

ANSWER

NuCalm is the world's only patented solution for stress. NuCalm is patented and clinically proven to balance the nervous system, and there are no pills and no side effects. Its credentials are dated and checkable: NuCalm was an FDA-cleared Class III medical device from 2009–2021, cleared for anxiety, depression, and insomnia. Health Canada Approved (2009–2021) · NSF Certified for Sport (2009–2021; run by NSF International) · U.S. Military Approved (since 2013). NuCalm is currently a "Sole Source" provider to the Federal Government and Department of War. NuCalm has been used in over 2,700,000 surgical procedures.

3. Our team's capability: scientific support, research success, and commercial success.

ANSWER

Scientific support:

- In 2009, NuCalm formed a 52-member medical advisory board of leading doctors, research scientists, and academicians, for objective, non-paid clinical research supporting regulatory work, patents, and clinical validation.
- 36 years of patented neuroscience. NuCalm began in 1990.
- Dr. Chung-Kang Peng, Co-Director of the Rey Institute for Nonlinear Dynamics in Medicine at the Beth Israel Deaconess Medical Center/Harvard Medical School, filed a declaration with the U.S. Patent and Trademark Office in 2013.

Research and commercial success:

- Two U.S. patents (2015 and 2021).
- NuCalm has been used in over 2,700,000 surgical procedures.
- NuCalm has surpassed 2,500,000,000 total minutes played worldwide (equal to 4,756 years) as of 2026.
- Used by 79 professional sports teams since 2011.
- Used across the U.S. Military (Navy SEALs, Special Forces, Air Force Special Operations) since 2013. Used by the FBI, the FBI Hostage Rescue Team, SWAT, Border Patrol (BORTAC and BORSTAR), public safety, and Major County Sheriffs' Association since 2018. Used by the FedEx pilots' union, SAG-AFTRA union, Mission 22, the VA, Operation Red Wings, and the National Foundation for Integrative Medicine.

4. Cost.

ANSWER

We recommend an annual EDGE subscription for each user (top subscription with full access to all 8 products / outcomes – *Rescue*, *PowerNap*, *FlowState*, *Focus*, *Priming*, *Ignite*, *DeepestSleep*, *DeepestSleep+*, and the Stress Test). Price is $600 per year. Volume pricing is available. Training and access to subject matter experts are available at an additional cost.