



# Instructions for Use

TMP-IFU-01

## WakeZ Instructions for Use

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### Manufacturer Contact Information

SC WakeZ Health Tech Ecosystem SRL

8, Pavel Dan Street, Cluj-Napoca, Romania

Website / IFU URL: <https://wakez.ai/ifu>

Manufacturer support email: [info@wakez.ai](mailto:info@wakez.ai)








Technical support email: [support@wakez.ai](mailto:support@wakez.ai)

Vigilance / serious incident reporting contact: [support@wakez.ai](mailto:support@wakez.ai)

Paper IFU requests: [support@wakez.ai](mailto:support@wakez.ai). Paper copies are supplied within 7 calendar days of request, or earlier where required for safe use or by applicable law.

### Symbols

WakeZ uses internationally recognised symbols where applicable. Symbols are used according to applicable harmonised standards, including ISO 15223-1 where relevant. Where a symbol is not self-explanatory, its meaning is defined below. Final graphical symbols must be inserted before release.

Symbol	Meaning	Explanation / use in WakeZ
	CE marking	Indicates conformity with applicable EU requirements after completion of conformity assessment.
	Medical device	Indicates that WakeZ is a medical device under Regulation (EU) 2017/745.
	Unique Device Identifier	Identifies the software medical device and applicable released configuration.
	Manufacturer	Identifies SC WakeZ Health Tech Ecosystem SRL as the manufacturer.
	Software release date	Identifies the release date of the latest CE-marked and approved WakeZ software build.
	Consult instructions for use	The user must read this document before use.
	Caution / safety information	Indicates important warnings, precautions or limitations.





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### Device label / electronic label information

Because WakeZ is a software-only medical device, the device label is provided electronically in the WakeZ application, in the regulatory information screen, and in these Instructions for Use. The same information may also be made available on the WakeZ website and in controlled release documentation.

Label particular	WakeZ label / e-label entry
Device name / trade name	WakeZ
Device type	Software medical device
Risk class	Class I under Regulation (EU) 2017/745
CE marking	
Medical device symbol	
Manufacturer	SC WAKEZ HEALTH TECH ECOSYSTEM SRL
Registered address	8, Pavel Dan Street, Cluj-Napoca, Romania
UDI-DI / UDI carrier	1314292001.1088 / electronic label
Basic UDI-DI	PP14292WAKEZ03
Software version / build	Version 1.2.13 (18)
Date of release of software version	2026-05-24
IFU revision and date of issue	Version 2, issued 2026-05-24
IFU URL	<a href="https://wakez.ai/ifu">https://wakez.ai/ifu</a>
Immediate safety notice	<b>WakeZ is not intended for clinical diagnosis, screening, monitoring, prediction, prevention, treatment, emergency use or clinical decision-making. Questionnaire responses and scores are not WakeZ diagnoses and must not be used to make medical or treatment decisions. WakeZ does not replace professional medical advice or care. Read the Instructions for Use (IFU) before use.</b>

The following MDR Annex I 23.2 particulars are not applicable to WakeZ because WakeZ is a software-only device: sterile state, sterilisation method, single-use status, reprocessing status, custom-made device status, medicinal substance incorporation, human or animal tissue incorporation, qualitative composition of substances introduced into the human body, implantable-device serial number, sterile packaging information and physical packaging integrity.

### Applicability of MDR Annex I, Chapter III, Section 23.4

These Instructions for Use have been prepared to include the applicable information required by Regulation (EU) 2017/745, Annex I, Chapter III, Section 23.4. For a software-only Class I device such as WakeZ, some requirements are not applicable because the device is not supplied sterile, is not implantable, does not contain medicinal substances, human or animal tissues, CMR or endocrine-disrupting materials, consumables, physical accessories, biological material, radiation-emitting medical components or substances introduced into the human body.



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Where a requirement is not applicable, this IFU states the non-applicability or addresses the related safety point through software-specific instructions, such as installation, compatibility, cybersecurity, data quality, user warnings, contraindications, troubleshooting, safe discontinuation of use and incident reporting. A detailed MDR Annex I 23.2 / 23.4 mapping is provided in Appendix A.

## Introduction

This document is the official user guide and Instructions for Use for WakeZ, a software medical device manufactured by SC WakeZ Health Tech Ecosystem SRL. It is recommended that users, healthcare providers, clinic staff and technical personnel read this instruction manual carefully before use. These instructions are written to be understandable by lay adult users while also providing the technical and operational information needed by healthcare professionals and support personnel.

WakeZ is a software-only system used with compatible Apple iPhone and Apple Watch devices, a secure WakeZ cloud backend and, where applicable, a clinician-facing web platform. WakeZ includes a publicly available observational pathway and a restricted-access haptic sleep-routine support pathway. The restricted-access pathway may be distributed through Apple TestFlight or another manufacturer-controlled channel, but it forms part of the WakeZ CE-marked device only when the specific software build, Apple Watch companion build, backend release and haptic-logic version are identified as released configurations under WakeZ technical documentation and release controls.

WakeZ is a Class I medical device under Regulation (EU) 2017/745 (MDR), subject to the manufacturer's conformity assessment, technical documentation, post-market surveillance, vigilance and quality-management obligations. The WakeZ solution bears the CE marking after completion of conformity assessment and release controls. The CE mark appears in these instructions, in the application environment and in other applicable product information.

These Instructions for Use are part of the information supplied with the device. The manufacturer keeps the electronic IFU available and up to date at <https://wakez.ai/ifu> and/or inside the application. For lay users in Romania, a Romanian-language IFU must be supplied or made available before market release. A paper copy may be requested using the manufacturer contact information above.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established. In Romania, the competent authority is the National Agency for Medicines and Medical Devices of Romania (ANMDDMR).

**Important Class I scope statement: WakeZ provides non-urgent sleep-architecture information, personal sleep-pattern information, optional self-reflection questionnaires and gentle haptic sleep-routine cues. WakeZ does not diagnose, screen for, directly predict, prevent, treat, monitor or cure depression or any other disease. WakeZ does not replace professional medical judgment and does not instruct healthcare professionals or users to make diagnostic or therapeutic decisions.**

## Device Description

### Intended purpose

WakeZ is a software medical device for sleep analysis. It is intended to provide information about the user's sleep architecture, including REM sleep architecture parameters such as latency, duration, proportion and fragmentation where available, and to support self-directed reflection on the relationship between sleep patterns and general mood



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and mental well-being. Where the user has consented to share sleep data with a partnered clinician, WakeZ may also support optional self-reflection questionnaires (sent by the partnered clinician after personal consideration and decision) and clinician-supported review of sleep-pattern information.

WakeZ includes a publicly available observational pathway containing sleep-summary and smart-alarm functionality, and a restricted-access haptic sleep-routine support pathway. The restricted-access pathway may be distributed through Apple TestFlight or another manufacturer-controlled channel, but it forms part of the WakeZ CE-marked device only when the specific software build, Apple Watch companion build, backend release and haptic-logic version are identified as released configurations under WakeZ technical documentation and release controls.

WakeZ provides optional, user-defined smart-alarm haptic cues (vibrations delivered through the Apple Watch) and/or restricted-access gentle haptic cues during sleep to help reinforce consistent sleep routines, support smoother waking and encourage healthy sleep-pattern regularity. These haptic cues are intended for sleep-routine and general well-being support only. They are not intended to treat depression, modify a diagnosed disease state, replace medication or psychotherapy, or provide a therapeutic intervention.

WakeZ does not directly provide information intended to be used to make decisions with diagnosis or therapeutic purposes. WakeZ does not diagnose, predict, monitor depression or any other disease, determine relapse, recommend treatment, adjust treatment, triage users, or replace clinician decision-making. Any clinical assessment, diagnosis, treatment plan, referral or follow-up remains the independent responsibility of a qualified healthcare professional.

The device is intended for adults aged 18-65 years who are regular nocturnal sleepers and who use compatible Apple Watch and iPhone devices. The software is non-invasive and functions by processing data obtained from compatible consumer devices, Apple Health-derived sleep information, and/or Apple Watch movement and heart-rate data depending on the WakeZ pathway being used. Sleep-stage classification and sleep-pattern processing are performed using controlled backend software and locked machine-learning models. The device does not self-learn or autonomously change its released algorithm during field use.

### Indications for use and intended use conditions

WakeZ is indicated for:

- Tracking sleep architecture and REM sleep metrics, including latency, duration and proportion where available, to help users understand their personal sleep organisation over time.
- Supporting adults aged 18-65 years who wish to recognise potential associations between changes in their sleep patterns and their overall mood, energy, stress and mental well-being.
- Supporting user self-awareness and self-directed lifestyle actions for the maintenance of general mental and emotional health.
- Providing optional gentle haptic cues to support a smoother wake-up experience and to help reinforce consistent sleep routines and healthy sleep-pattern regularity.
- Providing restricted-access haptic sleep-routine support to authorised users where access has been enabled by WakeZ and, where applicable, by a partnered clinician after independent suitability review.
- Providing clinicians, only with user consent, with contextual sleep-pattern summaries and questionnaire information that may support discussion with the user, without generating clinical instructions or automated recommendations.



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The term "supportive" in WakeZ documentation refers only to self-directed, general well-being actions and earlier personal awareness. It must not be understood as prevention, diagnosis, monitoring, treatment or cure of depression or any other medical condition by the device itself.

## Expected benefits

WakeZ is intended to provide informational and self-awareness benefits related to sleep architecture and sleep-pattern regularity. The expected benefit is that the user can view software-derived sleep summaries, REM-related sleep architecture information where available, sleep-session history and optional self-reflection questionnaire information in a structured and understandable format. This information may help the user with self-reflection regarding sleep, mood and general mental health.

Where the user consents to clinician sharing, WakeZ may provide authorised healthcare professionals with contextual sleep-pattern and questionnaire information for discussion with the user. WakeZ does not provide a diagnostic, therapeutic, disease-monitoring or emergency clinical benefit. WakeZ does not determine whether a medical condition is present, whether treatment is required, whether treatment is effective, or whether relapse or deterioration has occurred.

## Patient population

WakeZ is intended for adult users aged 18-65 years who are regular nocturnal sleepers and who use compatible Apple Watch and iPhone devices. The intended cohort includes users who wish to better understand their sleep architecture and its possible relationship with general mood, stress, energy and mental well-being.

For clinician-supported pathways, WakeZ may also be used by adults who are already in contact with a partnered healthcare professional, provided that the clinician independently determines that WakeZ is appropriate as a sleep-routine and sleep-awareness support tool. Clinician-enabled use does not change the intended purpose of WakeZ. WakeZ does not establish eligibility for diagnosis or treatment and does not determine whether a user should receive medical care.

WakeZ is not validated for children, older adults outside the stated range, pregnancy or breastfeeding, diagnosed sleep disorders, implanted cardiac/electrical devices, relevant cardiac rhythm disorders, severe psychiatric illness or acute psychiatric risk, shift work, polyphasic sleep patterns, or use with non-compatible devices.

## Intended users

User group	Role in WakeZ	Required capability / training
Primary lay user	Installs the iPhone and Apple Watch app, grants permissions, wears the watch during sleep, reviews sleep summaries and completes optional self-reflection questionnaires.	Adult user able to operate an iPhone and Apple Watch, read the supported language, understand onboarding, and feel or notice haptic cues.
Healthcare professional / clinician	May view user-approved sleep summaries, baselines where released, baseline flagging and deviation information where released and questionnaire responses in the web platform; may contact the user or invite the user for clinical assessment according to independent professional judgment.	Qualified healthcare professional. Must understand that WakeZ outputs are informational and are not diagnostic or treatment recommendations.



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User group	Role in WakeZ	Required capability / training
Clinic staff / authorised platform user	May assist with account setup, permissions, platform administration or workflow coordination under clinic policy.	Trained by clinic and/or WakeZ onboarding materials; access rights limited by role.
Manufacturer support and technical personnel	Maintain software services, assist users, investigate support tickets, manage releases, monitor security and perform controlled technical operations.	Trained under WakeZ quality management system procedures, confidentiality requirements, GDPR and cybersecurity procedures.

WakeZ provides healthcare professionals with access to monitoring data only when the user has authorised such access. Healthcare professionals can review sleep and questionnaire information as contextual information, but WakeZ does not assess the appropriateness of any diagnosis, therapy, prescription, clinical visit or emergency action.

## System composition and functional architecture

WakeZ is a complex software system composed of multiple tightly linked modules. The modules are part of one controlled WakeZ ecosystem and may be released, enabled or restricted according to user pathway, clinical partnership, software build and access rights.

Component	Availability	Main function
App Store iPhone application - observational pathway	Public App Store release, subject to release status	Retrieves Apple Health-derived sleep information, sends relevant data to the WakeZ backend, displays sleep summaries and released trend information. Enables use of a “smart alarm” (haptic cues delivered in an indicative predefined window before a user-defined alarm inside the app) to support gentle awakenings and a better morning routine.
Apple Watch companion app for App Store pathway	Paired with App Store iPhone app	Supports session coordination, Apple Health data activation/transfer and waking-window smart-alarm data collection for a gentle waking experience.
Clinician-facing web platform	Available to authorised partnered clinicians/clinic users	Displays user-approved sleep summaries, released trend information (baselines, flagging/deviations), questionnaire responses and workflow status; allows clinicians to send optional questionnaires and manage clinic workflow.
Restricted-access iPhone application - haptic sleep-routine support pathway	Restricted manufacturer-controlled access; may be technically distributed through Apple TestFlight or another controlled channel	Runs during the night, receives Apple Watch sensor data, communicates with cloud backend for live sleep-stage prediction and supports timing of gentle haptic cues.
Restricted-access Apple Watch companion app	Paired with the restricted-access iPhone app	Collects biometric data during the sleep session, communicates with the iPhone/cloud pathway, and delivers predefined low-intensity haptic cues.
Common WakeZ cloud backend	Shared controlled backend	Receives data from both iPhone app pathways, performs baseline analysis where released, trend/deviation logic where released, live sleep-stage prediction where enabled, secure storage and controlled software/model operations.



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## Operational pathways and platform cohorts

The WakeZ platform may organise end-users (non-clinician, non-support users) into operational pathways. These pathway names are workflow labels only. They are not diagnostic categories, do not indicate disease status, do not imply clinical severity, and do not change the intended purpose of WakeZ.

Operational pathway	Typical user situation	WakeZ app pathway	Permitted WakeZ role
Connected Care Pathway	Generally healthy or self-monitoring users who wish to understand sleep baselines and sleep-pattern changes in relation to general well-being, choosing to share WakeZ information with an authorised healthcare professional.	App Store observational app + App Store Apple Watch companion app.	User-facing: sleep summaries, self-reflection prompts where released, clinician-supported review if consented, and smart-alarm support.  Clinician-facing: contextual information for discussion with the user. WakeZ does not recommend clinical action.
Active Care Pathway	Authorised users for whom WakeZ has enabled restricted haptic sleep-routine functionality.	Restricted-access iPhone app + restricted-access Apple Watch companion app + backend haptic logic.	Sleep-routine support, live sleep-stage-informed haptic cue timing, sleep summaries and clinician-viewable context where consented. No diagnosis or disease management.
Continuity Pathway	Users who continue to use WakeZ over time, after an Active Care period, discontinuing their clinician-patient relationship, for sleep-pattern awareness and self-reflection.	App Store observational app + App Store Apple Watch companion app.	Longitudinal sleep-pattern awareness. No claim of maintaining remission, preventing relapse or treating residual symptoms.

## Principles of operation and mode of action

The App Store observational pathway uses Apple Health-derived sleep information and other authorised sleep-related data to calculate and display released sleep summaries and sleep-pattern information, in order to support self-reflection and encourage maintenance of general mood and mental well-being. The app displays sleep-related information to encourage self-reflection and general lifestyle awareness. The user may choose to share information with a WakeZ-partnered clinician.

The App Store Apple Watch companion app supports the observational pathway and the smart-alarm feature. For smart alarm operation, the companion app may collect or use active sleep-related information in an indicatively predefined final sleep window before the user's selected alarm time in order to support a smoother wake-up experience. The smart alarm is intended for comfort, routine support and a gentler morning experience. It is not a treatment.

The restricted-access haptic pathway uses the Apple Watch companion app to collect movement and heart-rate related data during the sleep session. The iPhone app transmits the data to the WakeZ cloud backend. The backend performs controlled, locked sleep-stage prediction and applies predefined haptic cue timing rules. The watch then delivers low-intensity haptic cues. These cues are designed to encourage healthy sleep patterns and support a healthy sleep routine. They are not designed to treat or modify a disease state. Access to this pathway may be technically distributed through Apple TestFlight or another controlled distribution channel. The module is part of the CE-marked WakeZ device



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only when the relevant build number, backend release and haptic-logic version are locked, verified, validated, approved and listed in the released WakeZ configuration.

The clinician-facing platform displays user-approved data, including sleep summaries, released trend information, questionnaire responses and relevant workflow status. The platform does not display instructions to diagnose, treat, escalate, medicate, discharge or otherwise manage the user. Clinicians may use the information as one contextual input in their independent professional judgment.

The cloud backend supports secure data reception, pseudonymised or otherwise appropriately protected storage, baseline analysis where released, optional questionnaire data management, live sleep-stage prediction where enabled, predefined haptic cue logic and controlled software/model release management. The model and haptic feedback logic are locked in production. No self-learning, autonomous clinical adaptation or unapproved functional change occurs during use. Any change to released sleep-stage logic, haptic timing logic, intended purpose, user pathway, risk control or output interpretation must be assessed under WakeZ change-control and regulatory-impact procedures before release.

### Outputs displayed by WakeZ

WakeZ displays only the outputs available in the released software configuration identified in this IFU. Functions under development, internal analytics, non-released dashboards or future features are not part of the CE-marked device unless they are explicitly listed in the released configuration and described in this IFU.

Output type	Meaning	Limitations
Sleep summary	A software-derived summary of sleep organisation and estimated sleep stages. <b>Displayed in the mobile app.</b>	Not equivalent to polysomnography and not intended to diagnose sleep disorders.
REM-related metrics	Information such as REM latency, REM duration/proportion and fragmentation, where available and data quality is sufficient. <b>Displayed in the mobile app.</b>	Metrics are informational and may be affected by device fit, signal quality, illness, medication, alcohol, sleep schedule and Apple Health availability.
“Baseline” trend	A user-specific longitudinal view comparing recent sleep nights against the user's own prior pattern. <b>Displayed only in the web platform, after user approval regarding clinician data review.</b>	Requires enough valid nights. Baselines may be unstable early in use or after major lifestyle changes.
“Flagging” - Deviation flag / pattern change	A non-urgent indication that recent sleep patterns differ from the user's own baseline. <b>Displayed only in the web platform, after user approval regarding clinician data review.</b>	Not a diagnosis, warning, prediction or clinical alert. It should prompt reflection, not medical decision-making. <b>Clinicians should always use their own judgement in making decisions about their patients.</b>
Self-reflection questionnaire score	A score generated from user-completed questionnaire answers or clinician-sent surveys, where enabled in the released configuration.	A questionnaire score is not a WakeZ diagnosis. <b>Clinical interpretation remains with the user's healthcare professional where applicable.</b>

### Self-reflection questionnaires

WakeZ may display optional self-reflection questionnaires, where enabled in the released configuration. These questionnaires are completed by the user and are intended to support personal reflection and, where the user has consented, discussion with a partnered healthcare professional.



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Questionnaire scores are not generated by WakeZ as a diagnosis. WakeZ does not diagnose depression or any other mental-health condition. A questionnaire score should not be used by the user to start, stop or change treatment, medication, psychotherapy or medical follow-up.

Questionnaire element	Released build output
Questionnaire(s) used	<p>Patient Health Questionnaire-9 (PHQ-9) for the general App Store environment, displayed in the appropriate menu inside the mobile app..</p> <p>Clinician-approved and -prompted questionnaire, for the restricted-access environment. Clinicians prompt the user to complete a questionnaire based on their own clinical judgement, the particularities of the patient and the specific context of the medical case.</p>
Displayed score	Numerical score is displayed. If applicable, it is shown alongside threshold context (e.g., "Score: [X], above threshold ([Y])" or "Low Risk").
Threshold logic	Informational threshold logic applied. Exceeding the threshold triggers a multi-page support and warning modal.
User-facing message after notable score	<p>"Thank you for completing our surveys. Although the scores do not provide a diagnosis, your answers suggest you might be going through a difficult time. If you feel unsafe or at risk of harming yourself, call <b>112</b> immediately."</p> <p>Includes in-app signposting to local resources (<a href="http://listapsihologi.ro">listapsihologi.ro</a> and <a href="http://sanatateamintala.ro">sanatateamintala.ro</a>).</p>
Emergency content	<p>The modal explicitly instructs the user to call <b>112</b> immediately if they feel unsafe or at risk of harming themselves. It also provides direct links to local emergency resources (<a href="http://sanatateamintala.ro/ro/pentru-urgente">sanatateamintala.ro/ro/pentru-urgente</a>) and mental health professionals (<a href="http://listapsihologi.ro">listapsihologi.ro</a>).</p> <p>May be displayed if self-harm or immediate-risk content is included or if questionnaire item logic requires escalation text.</p>

If a questionnaire response or score concerns the user, or if the user experiences persistent low mood, loss of interest, anxiety, distress, impaired functioning or sleep disturbance, the user should consult a qualified healthcare professional. If the user has thoughts of self-harm or harming others, or feels at immediate risk, the user should seek urgent help immediately through local emergency services, an emergency department, a crisis line or a trusted person. WakeZ is not an emergency monitoring system.

## Performance characteristics

WakeZ provides software-derived sleep-stage estimates and sleep-architecture summaries based on data obtained from compatible Apple Watch and iPhone devices and processed by the released WakeZ software configuration. The performance of the released sleep-stage model must be verified and validated against reference datasets according to WakeZ verification, validation and clinical-evaluation procedures before release.

Performance characteristic	Released value
Released model version	WakezSageMakerV0 and Apple native models
Sleep-stage output categories	Awake, Light Sleep, Deep Sleep, and REM Sleep
Epoch length used for classification	30 seconds



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Performance characteristic	Released value
Reference method used in validation	Polysomnography-labelled datasets (both publicly available and internal) scored according to AASM rules
REM detection performance	Minimum 72% accuracy compared to polysomnography in a 3-stage classifier (Awake/REM/NREM)
REM duration error	REM duration value is calculated - not claimed as accuracy metric. Dependent on REM detection performance.
REM latency error	REM latency value is calculated - not claimed as accuracy metric. Dependent on REM detection performance.
Minimum valid session duration	180 minutes (3 hours). A maximum safety cap of 960 minutes (16 hours) is also applied.
Data-quality exclusion threshold	Sensor data points with missing or zero heart rate values (0 BPM) are excluded.
Conditions under which analysis is withheld	Session duration < 3 hours, session duration > 16 hours, physics violations (duration exceeds wall-clock period by >10 min), missing HR data, or backend processing failure.

WakeZ performance is not equivalent to clinical polysomnography. WakeZ must not be used to diagnose sleep disorders, mental-health disorders or any other medical condition. Single-night outputs should be interpreted cautiously, and trend information requires multiple valid nights.

### Suitability check for clinician-connected or restricted-access use

Before enabling clinician-connected use or restricted-access haptic sleep-routine support, the partnered healthcare professional or WakeZ-authorized operator should verify that:

- the user is within the intended age range of 18-65 years;
- the user is a regular nocturnal sleeper;
- the user uses a compatible iPhone and Apple Watch model with supported iOS/watchOS versions;
- the user can wear the Apple Watch safely and comfortably overnight;
- no listed contraindication or exclusion applies;
- the user understands that WakeZ is informational and non-urgent;
- the user has completed onboarding, consent and permission steps;
- the software version, Apple Watch companion version, backend release and, where applicable, restricted-access build match the released WakeZ configuration;
- clinician sharing has been explicitly authorised by the user.

WakeZ does not determine clinical suitability for diagnosis, therapy, medication, psychotherapy, referral, emergency care or follow-up. Those decisions remain the responsibility of a qualified healthcare professional.

## Precautions and Safety Information

### Compliant use

Any inappropriate use is forbidden. WakeZ must be used only according to this IFU, the in-app onboarding, the current release notes and the stated intended purpose.



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The user shall:

- Use WakeZ only with compatible Apple iPhone and Apple Watch devices and supported operating-system versions.
- Only use non-defective devices and software builds distributed through authorised channels.
- Check before each sleep session that the Apple Watch is charged, paired and worn correctly.
- Verify that WakeZ appears operational before starting a night session.
- Keep Apple Watch and iPhone in good working condition and updated according to WakeZ and Apple instructions.
- Use one WakeZ account and one Apple Health profile per person. Device sharing can contaminate personal history and invalidate trend information.
- Review all warnings, contraindications, limitations and onboarding acknowledgements before first use.
- Not share restricted-access pathway invitations, TestFlight links, login credentials or Apple Watch/iPhone setups with another person.

WakeZ must not be used by itself to decide whether the user has depression or any other illness, whether treatment is needed, whether treatment is working, whether treatment should be stopped, whether relapse has occurred, or whether a clinical visit is unnecessary. These decisions require professional clinical assessment by a qualified healthcare professional.

## General safety instructions

### Device and data integrity

- Ensure your Apple Watch is charged and functioning properly before sleep tracking sessions.
- Regularly update the WakeZ app and Apple operating systems to receive security updates, compatibility updates and bug fixes.
- Verify that sleep tracking data appears reasonable. Contact support if you notice repeated anomalies, missing sessions or unexpected outputs.
- Do not rely on WakeZ outputs if you suspect the device, application, watch sensors, Apple Health integration or internet connection is malfunctioning.
- Do not uninstall, reset, or revoke permissions while a sleep session is active or while data are syncing.

### Proper use and limitations

- Sleep tracking accuracy may be affected by alcohol consumption, medications, illness, fever, stress, travel, unusual sleep environments, loose watch fit, tattoos or skin characteristics affecting optical sensors, irregular schedules and connectivity problems.
- WakeZ cannot detect all sleep-related events, including sleepwalking, nightmares, sleep apnoea, nocturnal seizures or REM sleep behaviour disorder.
- Do not make important health, medication, occupational, driving or safety decisions based on WakeZ outputs.
- Do not interpret single-night sleep data as clinically meaningful. Trends require multiple valid nights and must be interpreted cautiously.
- If the app indicates low data quality, incomplete sync or invalid session, do not use that session for interpretation.



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### Data privacy and security

- Use strong authentication methods on the iPhone, Apple Watch and WakeZ account.
- Do not share your WakeZ login credentials.
- Review data-sharing permissions regularly, especially permissions for clinician access, Apple Health and cloud synchronisation.
- Be cautious when exporting or sharing sleep reports with others. Shared reports may contain personal health-related information.
- Report suspected unauthorised access, lost devices or data concerns to WakeZ support promptly.

### Interface and operation

- Familiarise yourself with the app interface, onboarding screens, symbols and settings before relying on sleep tracking data.
- Pay attention to app notifications about low battery, sync issues, permissions, data quality or device connection problems.
- Contact support if the app interface becomes unresponsive, displays outdated information or repeatedly fails to sync.
- Do not try to bypass onboarding, contraindication checks, app permissions or clinician-access controls.

### When to consult a healthcare professional

WakeZ provides sleep analysis, self-reflection support and sleep-routine haptic cues. It does not replace professional medical diagnosis, treatment, emergency care, psychiatric care, psychotherapy, medication review or clinical follow-up. Restricted-access haptic functionality, where enabled, remains a sleep-routine support function and must not be interpreted as treatment or disease-management functionality.

Users should consult a qualified healthcare professional under the following circumstances:

- If low mood, loss of interest, anxiety, irritability, fatigue, sleep disturbance or other mental-health concerns persist or intensify.
- If sleep disturbances become chronic, are accompanied by significant daytime dysfunction, or raise concern for a sleep disorder.
- If repeated sleep-pattern deviations or questionnaire responses concern the user, family member or clinician.
- If the user is under the care of a mental health professional and wants to discuss WakeZ information in the care plan.
- If the user is considering starting, stopping or changing medication, psychotherapy or any medical treatment. WakeZ must not be used for this decision.
- If restricted-access haptic cues repeatedly disturb sleep, cause distress, increase worry, or are self-perceived as clinically meaningful.

**Urgent safety notice:** if you have thoughts of harming yourself or others, feel at immediate risk, or are in a mental-health emergency, seek urgent help immediately through local emergency services, an emergency department, a crisis line or a trusted person. Do not wait for WakeZ outputs and do not use WakeZ as an emergency tool.



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### Residual risks, warnings and undesirable effects

WakeZ is non-invasive and software-only, but residual risks remain. These are controlled through warnings, onboarding, data-quality gates, access controls, conservative wording and user instructions.

Risk / warning	Possible effect	Required user action / mitigation
Misinterpretation as diagnosis or treatment guidance	Users or clinicians may over-rely on sleep-pattern information.	Use WakeZ only for personal sleep awareness and self-reflection. Consult a professional for health concerns. Clinicians must apply independent judgment.
False reassurance from normal sleep outputs	A user may delay help despite symptoms.	Do not ignore symptoms because WakeZ appears normal. WakeZ is not designed to rule out depression or any condition.
Anxiety from sleep-pattern information	A user may become worried by sleep-pattern changes.	WakeZ information is non-urgent and not diagnostic. Treat it as information for reflection or discussion, not as a warning of disease.
Data quality failure	Incomplete or inaccurate summaries may be displayed or withheld.	Check watch fit, battery, permissions and sync status. Do not interpret low-quality sessions.
Accidental awakening or sleep disruption from haptic cues	A user may wake up, experience sleep fragmentation, feel disturbed or become concerned by overnight cues.	Disable haptic cues if they disturb sleep; contact support if repeated; do not interpret cue timing as a clinical signal; do not use the haptic pathway if sensitive to overnight cues.
Skin irritation from Apple Watch wear	Redness, itching or discomfort may occur.	Stop wearing the watch if irritation occurs and follow Apple guidance. Seek medical advice if irritation persists.
Privacy or access issue	Personal sleep/questionnaire information may be visible to unauthorised persons if credentials are shared or devices are lost.	Use strong authentication, do not share passwords, revoke access when needed, and report suspected breach.
Use outside validated population	Outputs may be unreliable.	Do not use WakeZ if contraindications apply unless a clinician and WakeZ release documentation explicitly permit a controlled pathway.
Use of expired or non-released restricted-access build	Functionality may stop, change unexpectedly or fall outside the released WakeZ configuration.	Use only the build identified by WakeZ as authorised for your pathway. If the build expires or access is removed, stop using that pathway and contact WakeZ support or the clinic.

Possible undesirable effects include worry, anxiety or over-attention to sleep data; false reassurance if the user assumes normal WakeZ outputs exclude a health problem; sleep disturbance, awakening or annoyance caused by haptic cues; reduced sleep comfort due to wearing Apple Watch overnight; skin irritation, redness or discomfort related to Apple Watch or watch band wear; frustration or confusion caused by missing, incomplete or low-quality data; and privacy concerns if the user shares device access, account credentials or reports with others.

### General warnings

- WakeZ is not a diagnostic or therapeutic system.



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- WakeZ is not an emergency service or crisis-detection system.
- WakeZ should not be used as a substitute for professional mental health care.
- WakeZ should not be used to determine whether a user has any illness, whether symptoms are improving, whether relapse is occurring, or whether treatment should be changed.
- WakeZ outputs are non-urgent and informational.
- Restricted-access haptic functionality is not a treatment pathway and must not be interpreted as therapy or symptom management.

## Contraindications and exclusions

ID	Contraindication / exclusion	Rationale / instruction
C1	Age under 18 years or over 65 years	Safety and performance have not been established outside the intended age range.
C2	Pregnancy or breastfeeding	Performance and benefit-risk balance have not been established in these populations.
C3	Diagnosed sleep disorder, including obstructive sleep apnoea, narcolepsy, idiopathic hypersomnia, REM sleep behaviour disorder, periodic limb movement disorder or restless legs syndrome	WakeZ is not intended to diagnose or monitor sleep disorders and may provide unreliable sleep-stage information in these cases.
C4	Nocturnal seizures, Parkinsonism with REM disturbance or other major nocturnal movement disorder	Movement and autonomic patterns may fall outside the validated operating conditions.
C5	Cardiac arrhythmia, significant conduction disorder, pacemaker, defibrillator or other implanted electrical/cardiac device	Heart-rate and movement-derived sleep estimates may be unreliable; haptic cues may not be appropriate.
C6	Severe psychiatric illness, acute psychiatric crisis, current suicidality, recent self-harm, inability to safely interpret self-reflection information, or any situation where sleep/mood information may increase distress without adequate support	WakeZ is not an emergency, diagnostic or therapeutic mental-health tool. Seek professional care. Use in these situations requires independent clinical judgment and must remain outside standard lay self-use.
C7	Medication or substance use that markedly alters sleep architecture, heart rate, movement or autonomic physiology, unless a clinician considers use appropriate as sleep-routine support	Outputs may be affected by beta-blockers, stimulants, sedative-hypnotics, some antidepressants/antipsychotics, alcohol or other substances. WakeZ must not be used to evaluate medication effects or treatment response. Contact your clinician to evaluate compatibility.
C8	Night-shift work, rotating shift work, polyphasic sleep or frequent daytime naps as the main sleep period	WakeZ is validated only for consolidated nocturnal sleep routines.
C9	Known inability to wear Apple Watch overnight safely or comfortably	Device fit and safe overnight wear are required.

## Software-only device: non-applicable physical-device requirements

WakeZ is a software-only medical device. It is not supplied sterile, does not require sterilisation, does not require disinfection before use, does not contain consumables, does not contain user-replaceable parts, does not require assembly, does not require calibration by the user, and does not generate biomedical waste.



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WakeZ is intended for repeated use by one user account linked to one Apple Health profile and one compatible Apple Watch/iPhone setup. WakeZ must not be shared between users, because this may compromise personal sleep history, trend information and privacy.

If the iPhone or Apple Watch is transferred, sold, recycled or used by another person, the user should first end any active WakeZ session, confirm data synchronisation, sign out or delete the WakeZ account as intended, revoke Apple Health permissions, remove clinician sharing if enabled, uninstall WakeZ, and follow Apple instructions for erasing or unpairing the device.

## System Requirements

### Hardware and handling

WakeZ requires compatible Apple iPhone and Apple Watch devices validated in the release notes. Where discrepancies exist, the more restrictive validated configuration applies until the IFU is updated.

- Compatible Apple Watch models: Apple Watch Series 6 or newer, Apple Watch SE 2nd generation or newer, and Apple Watch Ultra models running **watchOS 9.0 or higher**.
- Compatible iPhone models: iPhone 11 or newer running **iOS 16.0 or higher**.
- General handling: Store and operate the iPhone and Apple Watch according to Apple instructions and within Apple environmental specifications.
- Apple Watch battery: At least **75%** is recommended before starting a night session to support high-fidelity biometric data capture.

### Software configuration

Platform	Minimum / controlled requirement	Notes
Mobile device - iPhone	iOS 16.0 minimum, compatible iPhone model, sufficient storage, active Apple ID / App Store or TestFlight access.	Final requirements must match released build and SRS.
Wearable device - Apple Watch	watchOS 9.0 minimum, compatible Apple Watch model, sufficient battery (75%+) and storage.	The watch must be paired with the user's iPhone and worn during sleep.
App Store iPhone application	WakeZ Version 1.2.12	Built via React Native. Uses Apple Health-derived sleep data and supports observational pathways.
App Store Apple Watch companion app	Version 1.2.12	Built via Swift. Supports final-window smart alarm and session coordination.
Restricted-access iPhone application	TestFlight distribution: Version 1.2.12	Used only for controlled haptic sleep-routine support pathways. Part of CE-marked device only when exact build is identified as released configuration.
Restricted-access Apple Watch companion app	Version 1.2.12	Used for full-night haptic sleep-routine support where enabled.
Web platform	Modern web browser (Chrome, Safari, Edge) with active broadband internet connection.	Built via Next.js. For partnered clinicians and authorised clinic users only.



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Critical software dependencies include Apple Health, Bluetooth connectivity, internet access, iOS/watchOS background-processing permissions where applicable, WakeZ account authentication, and cloud backend availability. If these dependencies fail, WakeZ outputs may be delayed, incomplete or unavailable.

Apple TestFlight is used only as a technical distribution channel for restricted-access WakeZ builds. The regulatory status of a WakeZ module is determined by WakeZ release control, technical documentation, risk management, verification and validation, and inclusion in the released configuration, not by the distribution channel itself.

## IT network characteristics and IT security measures

Minimum technical requirements include:

- Bluetooth connectivity for communication between Apple Watch and iPhone.
- Sufficient storage capacity on both devices for app installation and temporary session data.
- Active internet connection for account access, cloud processing, updates, analytics synchronisation and clinician-platform functionality.
- Secure connection to WakeZ backend services using HTTPS/TLS 1.2 or higher, or a later security level specified by WakeZ release controls.
- Use of iOS/watchOS native security controls, app sandboxing and device-level authentication.
- Encrypted data in transit and controlled storage according to WakeZ data-protection and security procedures.
- Role-based access control for clinician platform users.
- User-controlled consent and data-sharing settings where applicable.

Users are strongly encouraged to keep their devices updated with the latest Apple security patches and WakeZ software releases, to use passcode/biometric device protection, to enable two-factor authentication where available, and to avoid using jailbroken, rooted or compromised devices.

WakeZ is designed to operate in a GDPR-governed environment. Users are informed of data processing through the privacy notice and consent process, displayed upon first use and onboarding. Personal data processing, data minimisation, access control, retention, deletion and data-subject rights are managed through WakeZ policies and technical controls, in line with EU regulations.

## Connected devices and interoperability restrictions

WakeZ relies on specific Apple hardware platforms that function together as the device sensing and processing chain. WakeZ is not compatible with Android devices, iPadOS-only operation or third-party wearables, and it is not designed to connect to or control other medical devices or accessories.

Connected platform	Supported configuration	Role
Apple Watch	Apple Watch Series 6 or newer, Apple Watch SE 2nd generation or newer, and Apple Watch Ultra models running <b>watchOS 9.0 or higher</b> .	Supplies movement and heart-rate related data during sleep and, when enabled, delivers low-intensity haptic pulses.
iPhone	iPhone 11 or newer running <b>iOS 16.0 or higher</b> .	Hosts the WakeZ app, receives/synchronises data, uploads encrypted data to the WakeZ backend and displays processed results.



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Connected platform	Supported configuration	Role
Clinician web browser	Modern web browser (e.g., Google Chrome, Safari, or Microsoft Edge) running on a standard desktop/laptop OS with an active broadband internet connection.	Used by authorised clinicians and clinic staff to view user-approved information.

## External influences, radiation, electromagnetic and material considerations

WakeZ software does not emit ionising or non-ionising medical radiation and does not introduce substances into the body. iPhone and Apple Watch radio, power, electromagnetic and material characteristics are those of the Apple hardware and must be considered according to Apple specifications. WakeZ introduces no additional patient-contact materials, leakage currents or physical connectors beyond the Apple hardware used by the user.

Users with known allergies or sensitivities to Apple Watch materials should consult Apple specifications and stop use if skin irritation occurs. Seek medical advice if irritation persists.

## Installation and Uninstallation

### Requirements before installation

- Ensure you have a compatible iPhone paired with a compatible Apple Watch.
- Maintain a stable internet connection during setup and keep Bluetooth ON for watch-phone synchronization.
- Sufficient battery charge. Apple Watch battery of at least 75% is recommended before starting a night session, as the high-fidelity biometric data capture is resource-intensive and expected to utilize approximately 35-40% of the battery overnight.
- Apple Health installed and functional for the App Store observational pathway.
- Valid WakeZ account and completion of onboarding, consent and permission screens.
- For the restricted-access haptic pathway, an invitation and authorised access are required.

### Install the App Store observational application

1. Open the Apple App Store on the compatible iPhone.
2. Search for WakeZ or use the official WakeZ installation link provided by the manufacturer or clinic.
3. Install the WakeZ iPhone application.
4. Install the Apple Watch companion app when prompted, or through the Apple Watch app on your iPhone by ensuring the "Show App on Apple Watch" installation toggle is enabled.

**Note: It may take up to 10 minutes for the app to sync and appear on your watch.**

5. Open the iPhone app and follow the on-screen prompts to register your profile, complete consent, and finish onboarding.
6. When prompted, grant requested Apple Health permissions. It is critical to tap "Turn On All" as read/write access to Sleep and Heart Rate is required to provide accurate insights.
7. Confirm Bluetooth and internet connectivity and run the in-app connection check if available.



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### Install the restricted-access haptic sleep-routine application

The restricted-access haptic sleep-routine application is not the general public App Store application. It is available only to authorised users through a WakeZ-controlled access workflow. The application may be distributed through Apple TestFlight or another controlled channel. For regulatory purposes, TestFlight is only the technical distribution mechanism. The module is part of the CE-marked WakeZ device only when the specific build has been released, locked, verified, validated and listed in the WakeZ released configuration.

1. Install Apple's TestFlight app on the iPhone from the App Store, if this distribution channel is used for your authorised build.
2. Open the official WakeZ restricted-access invitation link provided in your welcome email, or scan the provided QR code, and accept the invitation.
3. In TestFlight, tap Install for the WakeZ restricted-access iPhone application.
4. Install the corresponding Apple Watch companion app if prompted. If you do not see the app on your Apple Watch, open the TestFlight app on your iPhone, locate WakeZ, and ensure the "Show App on Apple Watch" installation toggle is enabled.

**Note: It may take up to 10 minutes for the app to sync and appear on your watch.**

5. Keep TestFlight installed only if required for access to the authorised WakeZ build and controlled released-module updates.
6. Open the iPhone app and follow the on-screen prompts to register your profile. Complete onboarding, permissions, contraindication checks, and haptic test instructions before the first overnight session. When prompted for Apple Health, it is critical to tap "Turn On All" to grant the required read and write access to Sleep and Heart Rate.
7. Do not share the invitation, app access, login credentials or device setup with another person.
8. If the build expires, becomes unavailable or shows that access is no longer authorised, stop using the restricted-access pathway and contact WakeZ support or the partnered clinic.

### First launch and permissions

On first launch, WakeZ will guide the user through:

- Sign-in or account creation: Open the iPhone app and follow the on-screen prompts to register your profile.
- Consent and onboarding, including Class I scope acknowledgement and non-diagnostic/non-therapeutic disclaimers.
- Contraindication/exclusion questions, where applicable.
- Apple Health access for the App Store observational pathway. When prompted, it is critical to tap "Turn On All" for Apple Health permissions. Read and write access to Sleep and Heart Rate is strictly required to provide accurate insights.
- Motion and Fitness, Bluetooth and Notifications permissions where required by the active pathway.
- Background App Refresh and Low Power Mode guidance for overnight reliability.
- Clinician-data sharing consent, where the user chooses to connect to a partnered clinic.
- Haptic cue test and configuration where the haptic pathway is enabled.



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### Uninstall / removing access

- iPhone app: long-press the WakeZ icon > Remove App, or remove through iPhone Settings.
- Apple Watch app: on iPhone open Watch app > My Watch > WakeZ > toggle off Show App on Apple Watch, or delete from the watch Home Screen.
- Restricted-access channel: open TestFlight > WakeZ > Stop Testing or follow WakeZ instructions, to remove the restricted-access build and stop future restricted-module updates. Removing the restricted-access build does not automatically delete all WakeZ account data or revoke Apple Health permissions.
- Revoke Health permissions: iPhone Settings > Health > Data Access & Devices > WakeZ > disable data types or Remove Access.
- Account/data deletion: use in-app Delete Account or contact WakeZ support according to the privacy notice.
- Hardware disposal: follow Apple recycling and local e-waste guidelines. WakeZ is software-only and creates no physical biomedical waste.

## Getting Started and Use Instructions

### Before you begin checklist

- Apple Watch is charged to around 75% every night and worn snugly on the wrist, with the sensor flush with the skin.
- Turn Always-On Display OFF to reduce screen glare during the night.
- Enable Silent Mode.
- Activate Sleep Focus / Sleep Mode to ensure accurate tracking, better battery stability, and a distraction-free experience.
- WakeZ is installed on both iPhone and Apple Watch, where applicable
- Bluetooth is ON and the iPhone and Apple Watch are nearby.
- Internet is available, preferably Wi-Fi, for sign-in, processing and syncing.
- Onboarding is completed, including consent, contraindication acknowledgement, permissions and any clinic/cohort steps.
- The selected pathway is understood: App Store observational/smart alarm pathway or restricted-access haptic sleep-routine pathway.

### Main workflow at a glance

1. Prepare: Charge the watch to around 75%, configure your watch settings (Always-On Display OFF, Silent Mode ON, Sleep Focus ON), confirm permissions, confirm pathway, and run a quick connection/haptic check if required.
2. Start the sleep session: Open the iPhone application first to prevent warnings, then open the Apple Watch app and tap the "Hack your sleep" button to begin.
3. Wear the watch overnight; WakeZ records or retrieves data according to the active pathway.



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4. Wake up and end the session: Tap the "Stop" button located at the top left of your Apple Watch screen upon waking up.
5. Sync data: Keep the watch and phone nearby with internet available. Open the iPhone app and remain on the Home page for a few seconds to trigger the final background sync.
6. Review the sleep summary: Navigate to the Stats page to review your Sleep Score, Sleep Stages, released trend information, and any non-urgent self-reflection prompts.
7. Complete optional questionnaire prompts: Navigate to the Forms page to complete morning surveys if you wish, or if your clinician has asked you to complete them.
8. Contact a healthcare professional for health concerns. Do not use WakeZ outputs as medical advice.

### App Store observational pathway - step-by-step sequence

1. Open WakeZ on iPhone and confirm that Apple Health permissions are granted.
2. Confirm that the Apple Watch is paired and worn during the intended sleep period.
3. Use WakeZ according to the in-app sleep or smart-alarm workflow. To initiate tracking, open the iPhone app first, then open the Apple Watch app and tap the "Hack your sleep" button. Confirm tracking has started by verifying the "Initiating sleep analysis" message and your live heart rate (BPM) are displayed on the watch screen.
4. If smart alarm is enabled, navigate to the Alarms page in the iPhone app, tap "Add an alarm," and set your preferred wake-up time and repeat days. Note that the smart alarm requires time to learn your optimal wake windows in order to support a final sleep-window assessment and gentle haptic wake-up cue.
5. After waking, tap "Stop" on the top left of the Apple Watch screen. Open WakeZ on the iPhone, remain on the Home page for a few seconds to allow data synchronisation, and optionally confirm the session is visible in the native Apple Health app.
6. Navigate to the Stats page to review your last-night sleep summary (including Sleep Score and Sleep Stages) and trend information when available. (If the page appears empty initially, allow a few seconds for the background sync to complete).
7. If a deviation or reflection prompt appears, or if you are completing morning surveys on the Forms page, treat it as non-urgent self-reflection information only.

### Restricted-access haptic sleep-routine pathway - step-by-step sequence

This pathway is available only to authorised users. It may be used in clinician-supported or controlled release workflows. It should not be interpreted as a treatment pathway.

1. Open the WakeZ restricted-access app on your iPhone first to prevent watch-level warnings, and then open the corresponding Apple Watch companion app.
2. Set a bedtime window or alarm if required by the build by navigating to the Alarms page and tapping "Add an alarm".
3. Tap the "Hack your sleep" button to begin. The watch will confirm that recording has started by displaying an "Initiating sleep analysis" message along with your live heart rate (BPM).
4. Keep the watch worn through the night and the iPhone nearby with Bluetooth enabled.



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5. During the night, WakeZ may process live sensor information and deliver predefined gentle haptic cues during configured sleep-stage windows.
6. In the morning, tap the "Stop" button located at the top left of your Apple Watch screen, then confirm session end according to the in-app instructions.
7. Open WakeZ on the iPhone and remain on the Home page for a few seconds to trigger the final background sync, waiting for the session to show Synced or a cloud checkmark.
8. Once you are fully awake, navigate to the Forms page to complete all available morning surveys. Then, navigate to the Stats page to review the summary (including your Sleep Score and Sleep Stages) and haptic cue log if available.
9. Do not interpret haptic timing, sleep-stage estimates or cue logs as treatment, treatment response, relapse information or diagnostic information.

## Clinician web platform workflow

Clinicians and authorised clinic users use the WakeZ web platform as part of the released WakeZ ecosystem, where enabled and where the user has consented to data sharing.

- Clinicians and authorised clinic users access the web platform using role-based credentials.
- The platform displays user-approved information only.
- The platform may show sleep summaries, released trend information, questionnaire status and questionnaire responses.
- Clinicians may send optional self-reflection questionnaires through the platform where this is part of the workflow.
- WakeZ does not recommend clinical action. The clinician independently decides whether to contact the user, schedule a visit, perform clinical assessment or take any other action.

## Controls, displays and signals

Control / signal	Location	Meaning
Start / End ("Hack your sleep" / "Stop")	Apple Watch	Begins or ends an overnight session where applicable. On the Apple Watch, tap "Hack your sleep" to start and "Stop" (top left) to end.
Connected / Ready	Apple Watch	Indicates a watch-phone link appears available.
Recording ("Initiating sleep analysis" & Live BPM)	Apple Watch	Indicates the sleep session is active. The Apple Watch will display "Initiating sleep analysis" alongside your live heart rate (BPM) to confirm tracking has begun.
Syncing / cloud check	iPhone	Indicates data are being transferred or uploaded.
Questionnaire icon	iPhone	Indicates optional self-reflection questionnaire availability (e.g., morning surveys on the Forms page) or clinician-sent questionnaire.



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## Performance verification quick self-test

Run this once during setup and after major updates:

1. Open WakeZ on Apple Watch and iPhone. Confirm the status shows Connected/Ready.
2. Start (tap the "Hack your sleep" button) and immediately end (tap the "Stop" button at the top left) a short test session if the active build supports this.
3. Verify that the test session syncs by remaining on the Home page, and then appears on the Stats page or native Apple Health app.
4. Confirm cloud sync with the internet available.

Acceptance criteria: data flow verification completed, cloud sync shows success and no unresolved error is displayed.

## Shut Down and Data Integrity

### Normal shutdown

- iPhone: Open WakeZ and confirm that the Home page shows no active session. Close the app if desired; it can remain in the background.
- Apple Watch: Open WakeZ and confirm that the status is Ready/Connected and not Recording. Press the Digital Crown to leave the app.

### Shutdown during an active session

1. Open WakeZ on Apple Watch.
2. Tap the "Stop" button located at the top left of your Apple Watch screen.
3. Keep the watch and iPhone close with Bluetooth ON until sync completes.
4. Open WakeZ on the iPhone and remain on the Home page for a few seconds to trigger the final background sync.
5. Wait for the session to populate on the Stats page, or show a cloud checkmark or success status.
6. Navigate to the Forms page to complete all available morning surveys if enabled and desired.

### Emergency stop

- If the watch app is responsive, tap the "Stop" button on Apple Watch and confirm.
- If the watch app is unresponsive, force-quit the WakeZ watch app according to the current watchOS method.
- If still stuck, restart Apple Watch using the Apple power-off procedure.
- If the iPhone app is unresponsive, force-quit the iPhone app and reopen WakeZ to allow sync.
- Force-quitting or restarting during an active session may end recording and may create a partial session.

### Quick shutdown checklist

1. Session ended on Apple Watch or iPhone with confirmation haptic or on-screen success.
2. Session visible on iPhone and marked Synced.



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3. No active error or attention indicators.
4. If powering down, uninstalling or switching devices, all sync, permissions and account actions are complete.

### Maintenance, Updates and Lifetime

WakeZ software requires no preventive maintenance beyond keeping the app, backend-compatible release and Apple operating systems updated. Updates are released periodically through the Apple App Store, controlled restricted-access distribution channels such as Apple TestFlight, or controlled WakeZ backend release processes. Updates should be installed according to WakeZ instructions to maintain compatibility, cybersecurity, safety and performance. Restricted-access builds should be updated only through authorised WakeZ release channels.

WakeZ software is not subject to reuse limitations in the same way as physical reusable devices. However, if an iPhone or Apple Watch is transferred to another user, all personal data must be deleted from WakeZ, the WakeZ account must be signed out or deleted as intended, Health permissions must be revoked, and the Apple Watch must be unpaired/reset according to Apple instructions. Multi-user use invalidates personal history and may compromise privacy.

WakeZ does not require manual calibration. Internal self-checks, data-quality checks and periodic updates maintain software operation. Users should ensure that Apple Watch sensors are not obstructed and that the watch is worn correctly.

#### User maintenance tasks

- Keep iOS, watchOS and WakeZ updated.
- Keep the Apple Watch charged and clean according to Apple guidance.
- Review WakeZ data collection/system permissions after updates or device changes.
- Check sync status after each session.
- Review release notes after significant updates.
- Contact support if repeated errors, data-quality failures, haptic issues or unexpected behaviour occur.

#### Manufacturer maintenance tasks

- Maintain backend services, security controls, uptime monitoring and incident response.
- Maintain controlled software release and model-release procedures under the WakeZ quality management system.
- Monitor post-market feedback, complaints, vigilance events and cybersecurity events.
- Maintain IFU availability, version control and release alignment with current software builds.
- Provide support and field safety communications where required.
- For restricted-access modules, maintain controlled build identification, access management, expiry handling, release approval, verification and validation records, backend compatibility records and version traceability.



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### Troubleshooting and Error Messages

The instructions for use list system messages, error messages and fault messages in groups. Some wording may vary by software build. If the app displays a message that is not listed here and is not self-explanatory, contact WakeZ support.

Message / issue	Meaning / possible cause	Action required
Low battery	Apple Watch may not last through the session.	Charge before starting or stop the session and recharge. Recommended Apple Watch charge is at least <b>75%</b> due to high-fidelity data capture.
"Open iPhone app first" warning	Attempting to start the session on the Apple Watch without opening the iPhone application first.	Open the WakeZ app on your iPhone first, then return to the Apple Watch and tap the "Hack your sleep" button.
Connectivity lost	Bluetooth or internet connection unavailable between the watch and phone.	Keep iPhone nearby, enable Bluetooth, restore internet connection, and reopen WakeZ.
Permissions missing / "Health Access Denied"	Required Apple Health (Sleep, Heart Rate), Bluetooth, Motion/Fitness, or Notifications permissions are disabled.	Open iPhone Settings > Health, find WakeZ, and tap " <b>Turn On All</b> ". Ensure Bluetooth and other requested permissions are granted.
Session pending sync / Empty Stats Page	Data is recorded locally but the background sync to the backend is incomplete.	Keep watch and phone nearby. Open the iPhone app and <b>remain on the Home page for a few seconds</b> to trigger the final sync.
Cloud processing unavailable / Network Error	Backend maintenance, local connectivity issue, or AWS service error.	Ensure your iPhone has an active Wi-Fi or cellular connection and try again later. If repeated, contact support.
Account authentication failed	Incorrect credentials, expired session token, or security lock.	Re-authenticate, reset password, or contact support.
Update required	The installed app build is deprecated and no longer compatible with the backend API or safety controls.	Update the app via TestFlight or the App Store before continuing use.
Unsupported device	iPhone, Apple Watch, or OS version (e.g., below iOS 16.0 or watchOS 9.0) is not validated for this release.	Use a compatible device or update the OS if supported.
Questionnaire unavailable	Questionnaire not enabled, already completed, expired, or not sent by clinician.	No action required unless your clinician explicitly instructed completion; contact clinic if needed.

### Quality control procedures

WakeZ includes built-in diagnostics to verify proper operation where supported by the active build:

- The app checks permissions and sync status.
- Checks may occur at app launch, session start, during active sessions and after session completion.
- Diagnostic limitations include inability to detect all hardware faults, all Apple Health issues or all external causes of poor signal.



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- Users are alerted when failures occur and should ensure both Apple Watch and iPhone are updated and properly paired.
- If troubleshooting measures fail repeatedly, users should contact WakeZ support.

### Electronic IFU, Paper Copy and Website Availability

WakeZ Instructions for Use may be supplied electronically through the WakeZ application and/or the WakeZ website, in accordance with applicable EU requirements for electronic instructions for use for medical-device software. The current IFU is hosted at <https://wakez.ai/ifu>. WakeZ maintains a documented risk assessment for the provision of the IFU in electronic form, including user access, website availability, version control, protection against unauthorised modification, readability, backup access and paper-copy availability.

A paper copy of the current IFU may be requested using the manufacturer contact details. WakeZ will provide the paper copy within 7 calendar days after receiving the request, or earlier where required for safety or by applicable law.

The electronic IFU is provided in a commonly used format readable with freely available software. The current IFU and previous applicable versions are maintained under WakeZ document-control procedures at <https://wakez.ai/ifu>.

Where WakeZ is made available to lay users in Romania, a Romanian-language version of this IFU must be supplied or made available before release. The English master may be used for internal control, professional review, competent-authority communication or translation control, but it does not replace the required user-language version where Romanian-language lay-user information is required.

### Serious Incident Reporting and Vigilance

Any serious incident that has occurred in relation to WakeZ should be reported to SC WakeZ Health Tech Ecosystem SRL and to the competent authority of the Member State in which the user and/or patient is established. In Romania, the competent authority is the National Agency for Medicines and Medical Devices of Romania (ANMDMR).

Manufacturer vigilance contact: [support@wakez.ai](mailto:support@wakez.ai).

Users should report suspected device-related safety issues, unexpected serious deterioration linked to device use, cybersecurity incidents that affect safe use, privacy incidents, repeated malfunction, or other serious device-related concerns. WakeZ is not an emergency system; urgent health or safety situations require emergency services or direct professional care.

### Disclaimer and Document Control

This IFU does not override the privacy notice, informed consent documents, clinician agreements, study protocol, App Store information, restricted-access module instructions, TestFlight access instructions or technical documentation. In case of conflict, WakeZ will correct and align controlled documents through its quality management system. Only software builds and backend configurations identified as released WakeZ configurations are part of the CE-marked WakeZ device. Pre-release, expired, withdrawn, unapproved or non-authorised builds must not be treated as standard WakeZ functionality.



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## Version History

Version	Date	Description of change
1	2025-06-18	First version.
2	2026-05-24	Rebuilt ANMDMR-aligned version.