Patient Instructions for Use

Somryst® Prescription Digital Therapeutic

Somryst Patient Instructions for Use

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Somryst App Version 2.x
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Manufactured by:

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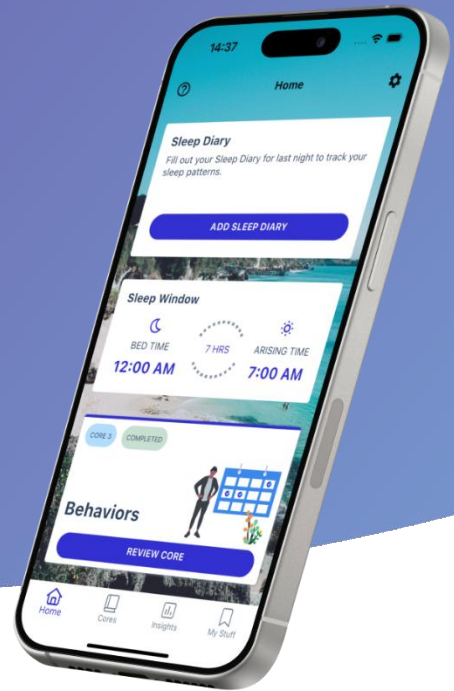IS - 105 Reykjavik
Iceland
Website: www.noxmedical.com

Rx Only
Caution: Federal Law restricts this device to sale by or on the order of a licensed healthcare professional in accordance with the law of the state in which that person practices to use or order the use of the device.

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Somryst®, a mobile app
is a 9-week Prescription Digital
Therapeutic (PDT) for
chronic insomnia.

What is Somryst®?

Somryst is a 9-week Prescription Digital Therapeutic (PDT) for chronic insomnia.

Somryst is a mobile application that you can use on your mobile device, either smartphone and/or tablet. Somryst is available by prescription only. A licensed Health Care Provider will prescribe Somryst® to you. You should only use Somryst when under the supervised care of a Health Care Provider.

Somryst delivers digital Cognitive Behavioral Therapy for Insomnia (CBT-I). CBT-I focuses on the behaviors, habits, routines, and dysfunctional thoughts that are part of sleep problems (regardless of the original cause of sleep problems).

CBT-I is typically delivered by a specially-trained clinician, either 1:1 or in group format. Standard delivery of CBT-I usually occurs in weekly sessions over 6-8 weeks. CBT-I is a scientifically proven behavioral treatment.

Somryst is designed to provide 6 Cores that deliver specific CBT-I treatment, listed below:

1. **Get Ready:** This Core sets the stage for your therapeutic experience. It lets you know what you will need to learn and do to improve your sleep.

2. **Sleep Window:** This Core is one of the most important ones. You will be guided through your first Sleep Window — a recommended Bedtime and Arising Time.

3. **Behaviors:** This Core helps you identify and change certain habits and behaviors that can interfere with sleep. Following these guidelines is a key part of CBT for insomnia.

4. **Thoughts:** This Core helps you understand how your thinking can contribute to insomnia. You will learn to identify and shift thought patterns.

5. **Education:** This Core helps you figure out what changes in your lifestyle and environment can promote better sleep.

6. **Looking Ahead:** This Core pulls together what you have learned, helps you prepare for the future, and teaches you what to do if you experience a relapse.

The Cores typically follow this structure:

- **Review:** After the first Core (Get Ready), each Core reviews the previous week's sleep, as collected in a sleep diary and homework (practiced strategies) from the previous week

- **Session Objectives:** Provides the basis for the treatment Core

- **Main Content:** Introduces new treatment strategies

- **Summary:** Wraps up the session by recapping above

- **Assignment:** Assignment of homework/strategies for upcoming week

Somryst includes a daily Sleep Diary for recording your sleep. The My Stuff section provides selected resources and elements from each Core for review. The My Stuff section for each Core is available after the Core is completed.

Intended Use / Indications for Use

Somryst is a prescription-only digital therapeutic intended to provide a neurobehavioral intervention (CBT-I) to patients 22 years of age and older with chronic insomnia. Somryst treats patients with chronic insomnia by improving a patient's insomnia symptoms.

Who Should Use Somryst

You should use Somryst if you:

- Are 22 years of age or older with chronic insomnia
- Are able to read and understand English
- Have regular access to a mobile device (such as smartphone or tablet)
- Are familiar with how to use mobile apps (applications)
- Are able to upload data periodically (In other words, you have internet/wireless connection access.)
- Are under the supervision of a Health Care Provider

The intended **operators** are health care providers who treat patients with chronic insomnia. The patient follows the treatment at home after having been granted access and introduction to the digital therapeutic device by a health care provider.

Who Should Not Use Somryst
(Contraindications)

Somryst uses sleep restriction and consolidation, limiting the time you spend in bed to match the amount of time you sleep. Sleep restriction and consolidation may worsen preexisting medical conditions. Because of this, it is not appropriate for everyone.

If you have any of the following conditions or disorders, you should not use Somryst:

- Any disorder exacerbated by sleep restriction (e.g. bipolar disorder, schizophrenia, or other psychotic spectrum disorders)
- Untreated obstructive sleep apnea
- Parasomnias
- Epilepsy
- If you are at high risk of falls
- If you are pregnant
- If you have any other unstable or degenerative illness judged to be worsened by sleep restriction delivered as part of Cognitive Behavioral Therapy for Insomnia

If you are unsure whether you have any of the conditions or disorders listed, speak with your Health Care Provider.
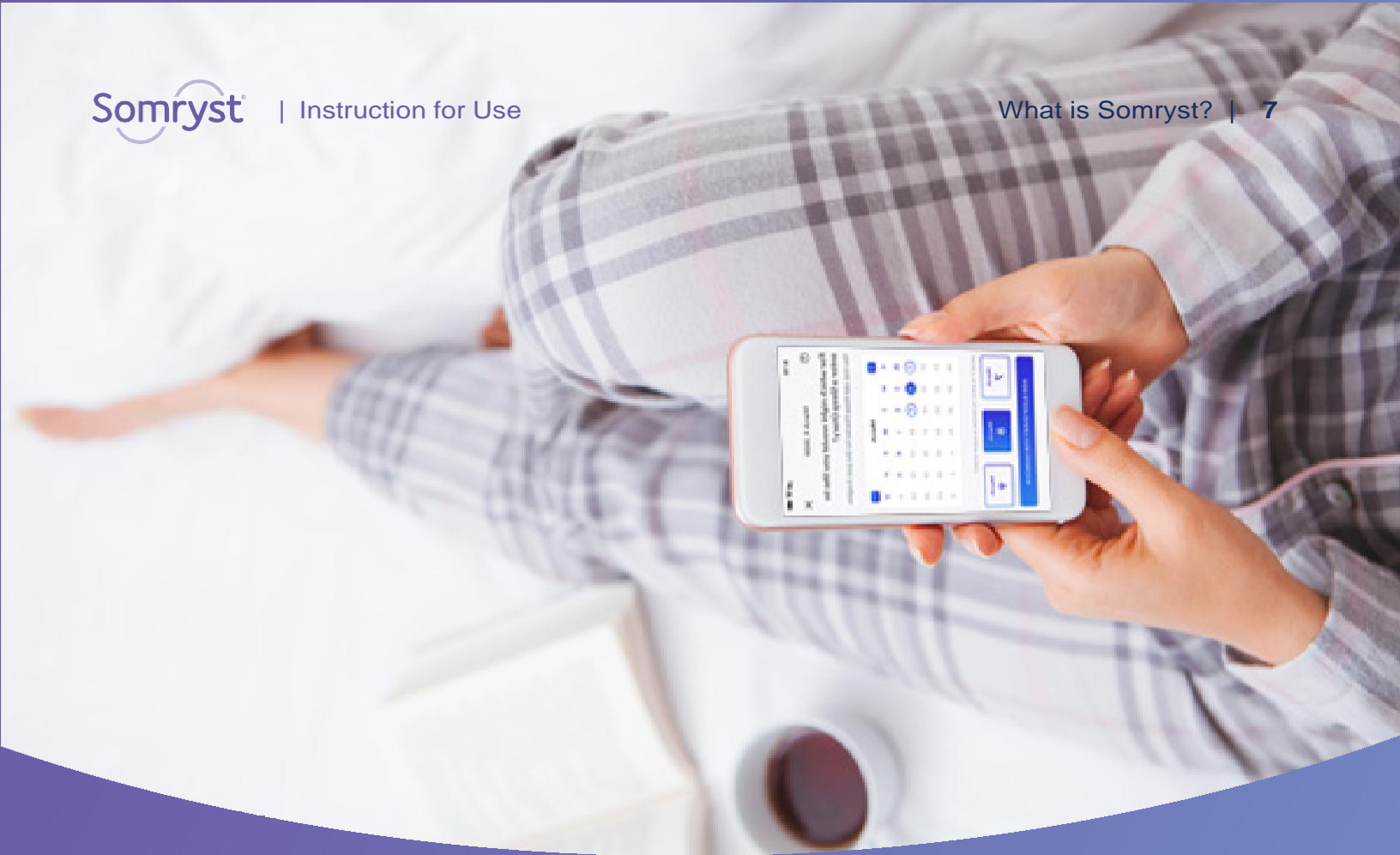
The Benefits of Somryst

Use of Somryst may help reduce the severity of your insomnia symptoms.

Benefits from the use of Somryst are only possible by following the instructions and practicing the exercises and strategies provided in the program. Treatment results may vary between individuals.

Risks associated with using Somryst are described in the "Safety Warnings" section on next page.

Safety Warnings

Somryst is not for everyone. You and your Health Care Provider should discuss whether Somryst is right for you.

- Somryst is not for emergency use. Please dial 911 or go to the nearest emergency room in the event of a medical emergency.

- Do not use Somryst to communicate severe or urgent information to your Health Care Provider.

- Somryst is not meant to be used as treatment except under supervision of your Health Care Provider.

- Somryst is not meant to be a substitute for any treatment medication.

- Somryst contains sensitive medical information about you. It is important that you protect your information by password-protecting your smartphone or tablet, ensuring no one else has access to your device.

- Sleep Restriction (and Consolidation) within Somryst can cause sleepiness, especially in the early stages of using the PDT. Somryst should not be used if you need to be alert or cautious to avoid serious accidents in your job or daily life. Examples include:

  - Long-haul truck drivers
  - Long-distance bus drivers
  - Air traffic controllers
  - Operators of heavy machinery
  - Some assembly line jobs

- Somryst is not intended for use as a standalone therapy.
- Somryst uses sleep restriction and consolidation, limiting the time you spend in bed to match the amount of time you sleep. Sleep restriction and consolidation may worsen preexisting medical conditions. Because of this, it is not appropriate for everyone.

Note: In the early stages of treatment, increased daytime sleepiness may be expected, but is usually temporary. However, if these experiences do not go away over a few weeks, please consult your health care provider as you may have a sleep disorder or medical condition other than insomnia. Also, at any point in the treatment, if you have trouble staying awake while performing potentially dangerous tasks (like driving) avoid these tasks or stop following the sleep restriction component of the therapy.
Note: For operational support, in case of use errors, cybersecurity events or other type of events, please contact support@noxmedical.com.

For best results with Somryst, read and follow the instructions provided in each core, and stay with the therapy until the end. When reporting your sleep results, giving honest and accurate answers is important.

Care Regimen and Self-Care

Following your Health Care Provider's instructions for care is always important. If you need help managing your condition, speak with your Health Care Provider.

How to Use Somryst

Downloading Somryst

Somryst is a mobile application (app) available for download on smartphones and tablets from the Apple App Store and Google Play Store.

Download and activate Somryst on a smartphone or tablet that is most convenient to you, as using Somryst on more than one device at the same time is not supported.

To download Somryst on your **iPhone** or **iPad**:

- Tap the App Store icon on the home screen.
- Tap the search icon and type "Somryst"
- Tap the "Get" button. You may need to enter your Apple ID and Password, or use Touch ID or Face ID to approve the download
- When Somryst is downloading, you will see the Somryst icon on your home screen and the progress of the download
- Tap the Somryst icon to open Somryst

To download Somryst on your **Android** phone or tablet:

- Tap on the Play Store app on your Android device
- Tap on the search bar and type "Somryst"
- Tap "Install"
- When Somryst is downloaded, either tap "Open" in the Play Store or, go to your home screen and tap the Somryst icon

Compatible Devices

Somryst is compatible with smartphone and tablet devices running:

- iOS version 15 or higher
- Android version 8 or higher

Please ensure your smartphone or tablet is running an OS version matching those above. If not, then please take the time to update your software version before downloading and using Somryst.

Getting Started

When your Health Care Provider prescribes Somryst to you, you will receive a prescription email. To activate your Somryst prescription, launch the Somryst app. Make sure you are connected to the Internet. You will be asked to enter your email address and password. This step will verify and activate your prescription.

When you log in for the first time you will be asked to enable your fingerprint or face recognition so that you can quickly log in and access Somryst offline. If you have not used Somryst for 30 minutes, Somryst will ask you to use your fingerprint, or hold the phone to your face to unlock the app. This allows you to quickly re-authorize access to Somryst. If biometrics (fingerprint or face recognition) are not supported on your device, the passcode or pattern that you can set on your device can be used instead.
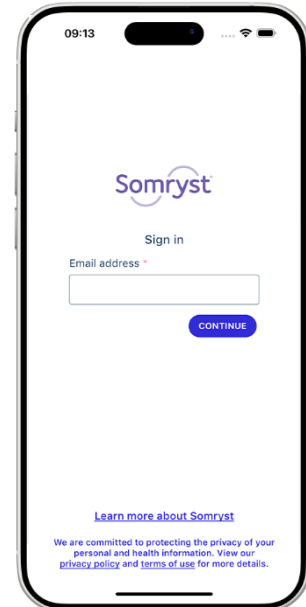
Navigating Somryst

This section describes how to navigate between the different areas of Somryst.

Basic Navigation

Use the tab bar at the bottom of your screen to move between the main sections of Somryst. The active section will be highlighted.

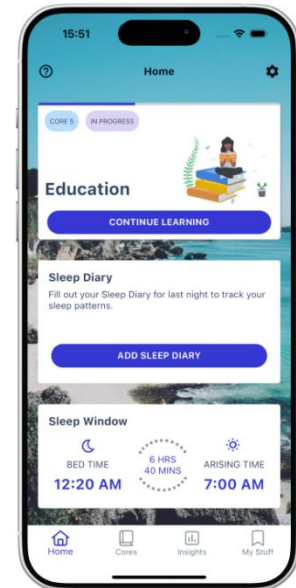Home   Cores   Insights   My Stuff

The arrows at the bottom of the screen lets the patient turn pages to read through the Core lessons. They can move forward or backward when the arrow is shown on the right or left side of your screen.

You can access Help from the top of the home screen. The Help section contains information about how to use Somryst, including these directions.

The **Settings** section allows you to log out of Somryst, reset your password, enable biometrics or device credentials to unlock the app, and delete the account.
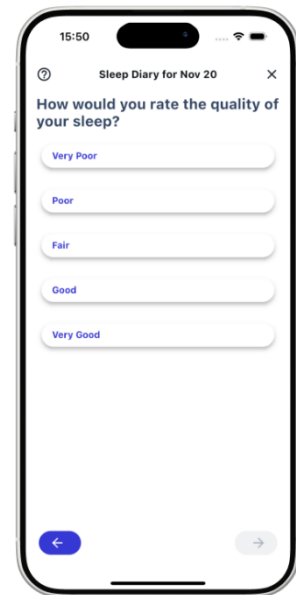
> **Use the tab bar icons**
> to move easily between
> different sections of Somryst.
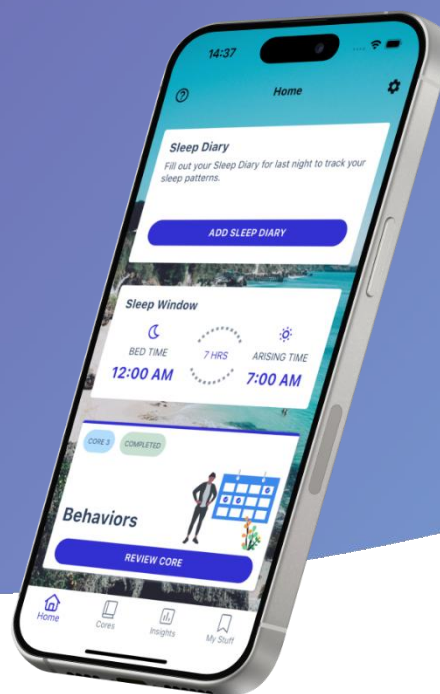
Using the Tab Bar

Use the tab bar icons at the bottom of your screen to move easily between the different sections of Somryst.

Tapping the **Home icon** takes you to the home screen. Tap this icon from anywhere in Somryst to return to the home screen.

The **Cores icon** takes you to the list of Cores. If a Core is available, it will be listed in blue. Cores that are not yet available are shown in gray with a lock icon.

The **Insights icon** takes you to the Sleep Diary and Wakecharts. This section also contains other useful information from their Sleep Diaries.

Tap the **My Stuff icon** to review important information from each Core.

Somryst Features

The most important sections of Somryst are described in the following pages.

Home

On the Home screen, you will find important information about where you are in the program and what you need to do next. When your Sleep Window is available, you can see your assigned bedtime and arising time. The number of Sleep Diaries you have entered for the week is also shown. You can also read an explanation of the Core for the current week. Tapping the blue button lets you start or continue the current Core.
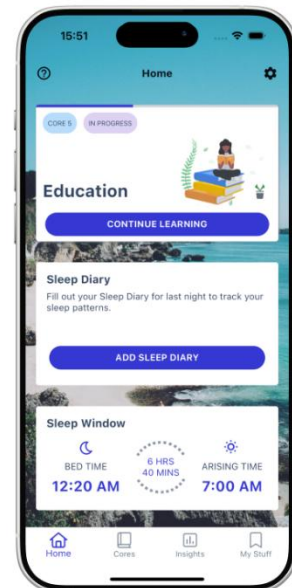
Sleep Diaries

By entering Sleep Diaries, you collect important information about your sleep patterns, and track your progress in the program. To give Somryst the most accurate information, complete your Sleep Diary every day. If possible, complete the Sleep Diary within one hour of getting out of bed in the morning. You can enter Sleep Diaries for the current day and the previous two days.

You can always access the Sleep Diary from the Home screen.

The Sleep Diary can be used to track sleep for people who are awake or asleep at unusual times. In the Sleep Diary, the word "day" refers to the time when you are awake. The term "bed" refers to when you usually sleep. You should not worry about giving exact times, and you should not watch the clock. Just give your best estimate when completing the Sleep Diary.
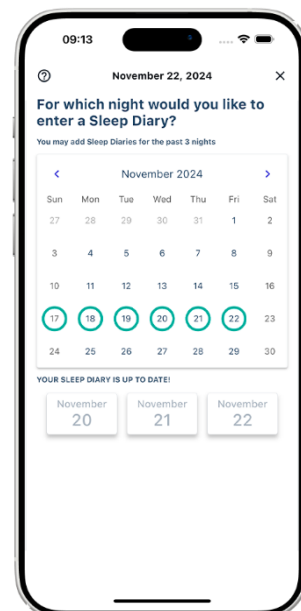
Cores

The Cores screen shows the 6 Cores of Somryst.

Cores provide new treatment techniques. When Cores are available, you will see a button that, when tapped, will begin the Core. Tapping the ⌄ icon will show a list of the topics in each Core. Cores that are not yet available show a gray lock icon.

If you leave the Core, you can pick it up again where you left off. Cores that you need more time to complete show a progress bar at the top.
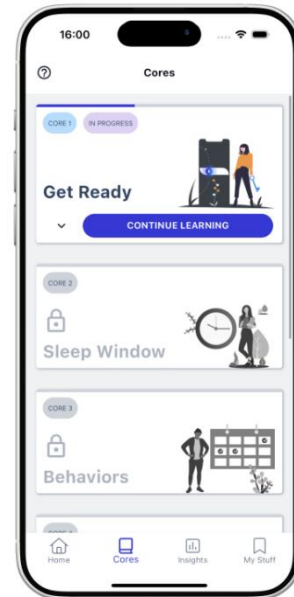
Insights

The Sleep and Wake Charts show your sleep patterns for the previous seven days. You can also view important information from your Sleep Diary, such as the quality of your sleep and any sleep medicines logged for the week.

Use the arrows at the top of the screen to show data for previous weeks.

My Stuff

My Stuff allows you to easily review important information from Cores you have already finished. You can always revisit this information from within the Core, but My Stuff provides a shortcut.

My Stuff is organized by Core. You can view My Stuff for each Core after you have completed that Core. Locked My Stuff lessons are shown in gray text with a lock icon.
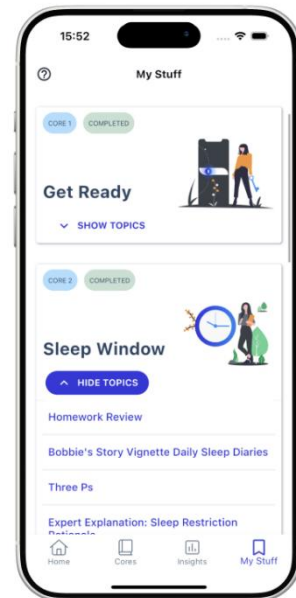
Notifications

Somryst will send notifications to help keep you on track with your treatment. You will receive reminders to log your daily Sleep Diary, as well as notifications when new Cores are available.

Notifications help you make progress toward improving your sleep.

Additional Resources

Security

It is your responsibility to secure your mobile device, smartphone or tablet. If you use an iPhone or iPad, use a passcode known only to you. If available, use Touch ID or Face ID. If you use an Android phone or tablet, use passcode or pattern, and enable face or fingerprint-unlock if available.

It is also necessary to update your phone or tablet operating system when recommended by the platform vendor (Apple or Google). Important security updates are included in these upgrades. The vendor will do this by notifying you on your device that an update is available for download and install.

Replacing Your Device

If you need to replace your smartphone or tablet, download Somryst again from the Apple App Store or Google Play Store. Log-in with your email address and password. Your progress in Somryst will be saved and you will be returned to current Core.

Updating Somryst

If an update is available for Somryst, an alert will appear when you next open Somryst. To update:

- Tap "Upgrade Now" to confirm that you would like to install the update.
- You will be taken to the Somryst app in the Apple App Store or Google Play Store.
- Select "Update" next to the Somryst app
- Tap the Somryst icon to open and use Somryst.

If you would like to set up automatic app updates on your smartphone or tablet, visit the following web pages for instructions:

- Apple Support
- Google Play Support

For instructions on how to update the operating system (iOS or Android) of your phone or smart device, visit the following web pages:

- iOS Updates
- Android Updates

Traveling with Somryst

When traveling, you should follow the instructions below to ensure you can still use Somryst:

- Your date and time settings should be automatic. When you connect to a new network, the phone or smart device updates your time zone.
- If the time zone does not automatically adjust, go to the date and time settings to find the correct time zone, or to set the time zone back to automatic.
- Turning off cellular data will allow Somryst to be used without a network.
- An internet connection is required to login with your email address and password and update the server with new data, including Sleep Diaries and Sleep Window. Before turning off the cellular data, make sure you are logged in to the app and check that you have enabled the biometrics or device credentials (passcode or pattern) in the app.
- You will not be able to update Somryst unless you are connected to a cellular data or Wi-Fi network.

Support

For additional support you can contact your Health Care Provider, or contact Nox Medical support at support@noxmedical.com.

Decommissioning and Disposal

To delete Somryst on your **iPhone or iPad**:

- Touch and hold the app.
- Tap Remove App.
- Tap Delete App, then tap Delete to confirm.

To delete Somryst on your **Android** phone or tablet:

- Tap on the Play Store app on your Android device.
- At the top right, tap the Profile icon.
- Tap Manage apps & devices and select Manage.
- Select the Somryst app.
- Tap "Uninstall".

For further instructions on how to delete the application, visit the following web pages:

- Apple Support
- Google Play Support

If there are any questions or assistance is required regarding the decommissioning and/or disposal process, including the retrieval or deletion of user data, please contact support@noxmedical.com.

Ending Your Prescription

The duration of each prescription is 9-weeks. Your prescription will end automatically, based on your prescription start date. Additional 9-week access to the Somryst therapy may benefit you, as chronic insomnia is a chronic disease.

Security Information

Somryst complies with the following security standards and guidelines:

- IEC 81001-5-1:2021 Health software and health IT systems safety, effectiveness and security – Security - Activities in the product life cycle

- IEC 82304-1:2016 Health Software – General requirements for product safety

- ANSI/AAMI SW96:2023 Standard for Medical Device Security – Security Risk Management for Device Manufacturers

The data storage on the cloud server has the following certifications:

- ISO 27001

- SOC2

- HITRUST

Somryst Ecosystem

Somryst ecosystem consists of a mobile application (Somryst) and Cloud Storage. Data is sent from the mobile device to the cloud storage for review.
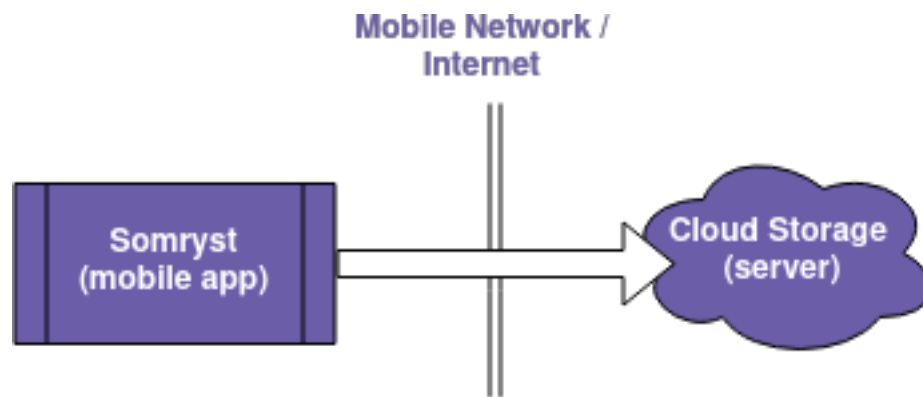
Data at Rest

The Cloud Storage is encrypted. The encryption used is an industry standard AES-256 data encryption.

Data in Transit

All Mobile Network/Internet data is transferred using encrypted endpoints (on port 443). No non-encrypted endpoints are provided for data communication.

The endpoint encryption uses TLS 1.2. The connection is encrypted using 256-bit encryption. SHA1 is used for message authentication and DHE_RSA as the key exchange mechanism.

Cloud Backups

All data is backed up both fully and incrementally. Incremental backups are performed daily, weekly and monthly with full recovery at least annually. Backups are tested at regular intervals to ensure successful recovery of data.

Cloud System Monitoring

Best practices for system monitoring are employed to ensure the security and stability of the system. AWS Inspector, CloudWatch and CloudTrail are used to monitor the systems for vulnerabilities, unusual activities and performance issues. Wazuh is used to monitor the logs for unusual activities or unauthorized file system changes. All these systems can generate alerts and block potentially threatening IP addresses.

Cloud Intrusion Detection and Prevention

To ensure that unauthorized people and services do not gain access to the platform, several intrusion detection and prevention measures have been implemented.

Log files are monitored to detect and prevent brute force attacks. Log files are monitored to detect multiple failed attempts to try to access the system and then block the IP of the calling system when this occurs.

User Configuration

To ensure seamless operation of the Somryst mobile application, the following security measures may need to be implemented by the user in case the mobile device or the home network is protected with e.g. a firewall application:

- Whitelisting of *.noxhealth.com (the asterisk means that subdomains shall be included) in the user's local firewall configuration

- Allowing outgoing traffic on port 443 to *.noxhealth.com in the user's local firewall configuration

Security Updates

All vulnerabilities notified / detected are assessed using the CVSS[1]. The score ranges between 0 and 10 and Security Updates are issued according to the following:

- CVSS 9.0-10.0: Critical – turn off service until the vulnerability has been patched.

- CVSS 7.0-8.9: High – Fix within 2 days.

- CVSS 4.0-6.9: Medium – Fix within 1 week.

- CVSS 0.1-3.9: Low – Fix within 4 weeks.

- CVSS 0: None – No action.

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[1] The Common Vulnerability Scoring System (CVSS) is a method used to supply a qualitative measure of severity.

Security updates are delivered via Google Play Store / Apple App Store. All installation packages are digitally signed by Nox Medical to guarantee the security and integrity of their content.

Vulnerabilities

No vulnerabilities have been identified that can affect the cybersecurity or safety of the device.

The vulnerability process used complies with the ANSI/AAMI SW96:2023 Standard for medical device security using methods described in the AAMI TIR57:2016 guidance – Principles for medical device security.

Software Bill of Materials (SBOM)

The Software Bill of Material (SBOM) is provided as an IFU Addendum to this document and is available upon request. The SBOM may be maintained more regularly than the product under scope and it is therefore recommended to use the latest version when reviewing the content.

Please reach out to support@noxmedical.com for full disclosure of the latest version of the Software Bill of Material for the product. The Software Bill of Material is updated with every product release / patch / vulnerability detection and is available both in a human readable and a machine-readable format.

Description of Symbols and Abbreviations

PDT	-	Prescription Digital Therapeutic
CBT-I	-	Cognitive Behavioral Therapy for Insomnia
HCP	-	Health Care Provider
OS	-	Operating System
UDI: (01)15694311112112(8012)VVvvrr	-	Unique Device Identifier (UDI): the Application Identifier (01) indicates the device identifier (DI) (i.e. "15694311112112"), the Application Identifier (8012) indicates the software version (i.e. "VVvvrr")
Rx Only	-	US federal law restricts this device to sale by or on the order of a licensed medical practitioner.