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# INSTRUCTIONS FOR USE

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Address 130 Miners Drive, Suite 101  
Lafayette, CO 80026  
United States

Sana Health Inc.  
IFU Document # PRT-0081  
Released: May 13, 2020

info@sana.io Email  
www.sana.io Web

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## PURPOSE OF THIS DOCUMENT

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This document is intended to help new users of the Sana device to understand the device, how to use it safely and to provide other information that may be helpful to gain the most benefit from the device.

It contains important information on who should use the device, how and when it should be used and what to expect during use. Please read this document carefully before using the Sana device and refer back to it as needed.

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## INTENDED USE

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**The Sana device is intended for use to enhance rest and relaxation in healthy adults.**

This may include such uses as:

To clear a busy mind

To support enhanced rest and relaxation

To improve sleep management

To reduce feelings of stress

To enhance recovery from fatigue

Note: The Sana Device is not approved by the FDA for the treatment of any specific medical condition.

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## DEVICE DESCRIPTION

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The Sana Device is a simple mask and headphones you wear on your head. The device uses audio visual stimulation to increase balance between the left and right side of your brain leading to greater relaxation.

Ongoing use of your Sana mask resembles the effect of long-term meditative practices which leads to a more restful state overall. Sana can clear a busy mind and accelerate mental and physical recovery.

The underlying mechanism of action for the Sana device is Audio Visual Stimulation (AVS), a form of neurofeedback. This is a form of drug-free intervention that has been used for both performance enhancement and fatigue management for decades and has been shown to be safe and effective.

The Sana device contains a sensor that contacts gently to your forehead to measure your heart rate variability (HRV). This is used by The Sana device algorithm. Heart rate variability measures your state of relaxation.

The Sana device is physically comprised of a rigid outer layer that sits furthest from your head, which provides the structure for the device and shuts out most of the ambient light. On the inside of the device, sitting against your skin, is a soft, non-allergenic formed foam that provides comfort and excludes external stimuli during treatment. The HRV sensor is also mounted on this inner surface. Between the structural outer part and the soft

inner layer is mounted circuitry and components to store and run the program, and the necessary lights and sound required to deliver it. The Sana device is controlled by an 'app', allowing you to log your progress. The app connects to the device via standard Bluetooth connection. Finally, the device contains a small rechargeable battery used to power the device. The Sana device is supplied with a standard micro-USB cable, which can be plugged into a normal 110V outlet connection to enable re-charging.

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## PACK CONTENTS

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Your Sana device will be supplied pre-packaged in a re-usable carrying case. The case will contain:

- One Sana with head-strap pre-fitted
- One charger (Micro USB, max 5V; 1.2A output). Only use supplied charger to charge device.
- One information card – please keep this for reference
- One Quick Start Guide
- One set of headphones with standard plug-in jack. You may use your own headphones or the ones supplied. Cordless (Bluetooth) headphones cannot be used.

You will also need to download the Sana Relief app Google Play (Android) or iTunes App Store (Apple) and register your account.

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## CONTRAINDICATIONS

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This device is not for use by:

- Persons under the age of 18
- Pregnant women
- Persons with a history or presence of photo-sensitive epilepsy or other light-sensitive conditions
- Persons with a history or presence of condition(s) that may affect balance, such as seizure disorders, tinnitus or vertigo
- Persons who are visually or hearing impaired (deaf), including those with a significant difference in hearing between ears or sight between eyes
  - Use of the device by persons with colorblindness is permitted provided the perception of color is reasonably even in both eyes
- Not to be used if the skin around the eyes in the area of the device is broken or inflamed. Should irritation occur based on contact of skin to the Sana device, discontinue use and seek advice from a healthcare professional.



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## GENERAL WARNINGS AND PRECAUTIONS

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- WARNING: Do not use device when in a situation where lack of normal vision and hearing may be unsafe, such as driving or walking
- WARNING: Do not wrap headphones around neck – choking hazard
- WARNING: Do not use device when charging. Always disconnect the device from the charger before use
- WARNING: No modification of this equipment is allowed
- CAUTION: Keep Dry
- CAUTION: Use both headphone earbuds for maximum therapeutic effect
- CAUTION: Do not disassemble the device
- CAUTION: To prevent possible hearing damage, do not listen at high volume levels for long periods.
- CAUTION: Use of the device may make you drowsy. Avoid driving or operating machinery immediately after use until you understand how the device affects you. Use of alcohol or other substances that may affect concentration may increase drowsiness. Avoid or limit alcohol or use of substances known to impede function when using the device. Consult your physician before using this device with prescription drugs that may impact concentration or balance.



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## INTENDED USERS

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The Sana device is intended for use by generally healthy adults who wish to improve their ability to rest, relax, or improve their sleep habits. The Sana device is intended for use at home, or when traveling, such as on airplanes and hotel rooms.

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## RISKS AND BENEFITS

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The Sana device has been in development for over twenty (20) years, and no known serious risks have been identified. If you have concerns about the safety of the device, or you feel unwell during or after use, you should discontinue use immediately and contact Sana Customer Success at 720-310-3370 or [support@sana.io](mailto:support@sana.io).

Stopping use of the Sana device mid-way through a therapy session has no known risks. You should stop using the device immediately if you are concerned or feel unwell; you do not need to wait for the session to end.

During a session, you should expect to see pulses of amber light through your closed eyelids and hear pulses of sound through the headphones. The speed, patterns and sequence of these pulses of light and sound will vary through the 16-min program. The program starts relatively fast and then progressively slows through the 16 minutes.

Some people feel relief on first use, while others require up to 5 session until your brain patterns get used to the device audio-visual inputs. This is quite normal, and each individual varies. During this training process, the



brain will often optimize balance, hearing and visual processes - this can feel a little unsettling, a bit like stepping off a boat onto dry land. This is normal, and by the fifth use should have gone away. If at any point it feels too much, or if these feelings don't go away, please discontinue use and contact Sana Customer Success for advice.

The soft cushion that sits against your face is made of fabric-covered polyurethane foam in regular use in consumer electronics and wearable devices. It is very unlikely that you will have any reaction to this material, but if you do; discontinue use and contact Sana Customer Success.

The sound is delivered through headphones. You may use the ones supplied or your own. You can adjust the volume. The maximum sound level is limited to 60dB (maximum normally available through commercial earphones), which is well within levels that are normally considered safe to your hearing.

The light is transmitted at low frequency (0.5Hz – 10Hz). The maximum intensity of light is around 35LUX (similar to the very edge of a candle flame). You can adjust how bright the light is. By contrast a bright summer day can exceed 32,000LUX. Vision damage from bright lights is complex and cannot be easily assigned a value of LUX, but generally intensities of less than 5,000 LUX are considered very low risk of causing damage to your eye.

The device is manufactured in the USA.

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## PROPER USE AND USE SITUATIONS FOR THE DEVICE

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**The Sana device is intended to be comfortable to wear and should be used in a place where you feel relaxed and at ease. Use the device in a comfortable location where you can safely have both hearing and sight interrupted, such as a lounge chair or your bed.** You should remove eye-glasses and other bulky headwear prior to using the device.

The device may make you sleepy, so make sure the location is comfortable and safe for you to relax and potentially fall asleep. Please do take the time to adjust the device and your position for comfort and relaxation. We advise you to be in a quiet place of rest, such as a comfortable chair or your bed, ideally reclined to at least 30-degrees and with your head and neck supported.... Anywhere you might normally go to take a nap.

You may use the device as often as you like. We recommend that you use the device any time you feel overly fatigued.

The device also helps relax you towards sleep. Sleep is very important to all of us. We recommend you use the device in bed each night right before you want to go to sleep. If you wake in the night, you may use the device to help you get back to sleep.

**WARNING: Do not use device when in a situation where lack of normal vision and hearing may be unsafe, such as driving or walking**

WARNING: Do not wrap headphones around neck – choking hazard

CAUTION: To prevent possible hearing damage, do not listen at high volume levels for long periods.

CAUTION: Use of the device may make you drowsy. Avoid driving or operating machinery immediately after use until you understand how the device affects you. Use of alcohol or other substances that may affect concentration may increase drowsiness. Avoid or limit alcohol or use of substances known to impede function when using the device. Consult your physician before using this device with prescription drugs that may impact concentration or balance.

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## EXPECTED OUTCOMES FROM USE OF THE DEVICE

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The Sana device is intended for use by generally healthy adults who wish to improve their ability to rest, relax, or improve their sleep habits. The Sana device is intended for use at home, or when traveling, such as on airplanes and hotel rooms.

Expected benefits include improved sleep management, calmer thoughts, with a quieter mind, enhanced rest and ability to relax, reduction in feeling of stress and enhanced ability to recover from fatigue.

You should see benefit within the first few uses of the device. The effects may last longer and be more effective over time, so continued and regular use of the device is important. We recommend 1-2 uses per day as part of your normal routine, more as needed, including one use as you go to sleep at night.

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## OPERATING INSTRUCTIONS

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A video showing you how to use the device can be found here:

<https://www.sana.io/instructions-sana-device>

### Operating Conditions:

Temperature	+5°C to +40°C
Relative Humidity	15% to 90%, non-condensing
Atmospheric Pressure	700 hPa to 1060 hPa

CAUTION: Keep Dry



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## FIRST USE

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The Sana device will come packaged in a re-usable soft case with an outer label. You can remove the label, but please keep the case to store the device. Please check the device is not damaged and the case contains one device, one set of headphones and one charger. You may use the headphones supplied or your own, pick a set that is most comfortable to you; in-ear or over-ear are both appropriate, but the headphones must be plug-in (not cordless Bluetooth). Keep the chargers (and the headphones you want to use) in the case with the device so they don't get lost.



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## CHARGING

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The Sana device contains a rechargeable battery. You will need to re-charge the device when it is not in use. The battery will store enough charge for 2 to 3 days of normal use, but we recommend you keep it charged up.

To charge the device, plug the provided micro-USB connector into the port on the bottom of the device and plug into any normal electrical outlet. Charging can take up to 4 hours. Only use supplied charger to charge device, to avoid possible harm to the device.

When the device is charging, the lenses will illuminate blue. When fully charged, the blue lights will turn off.

To stop charging, simply pull the connector out of the device.

**WARNING:** Do not use device when charging. Always disconnect the device from the charger before use

**NOTE:** if the device needs to charge but you want to conduct a therapy session, charging for approximately 15 minutes will provide enough battery life for a single session.



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## TURNING ON / OFF

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When you want to use the device, attach your headphones and slide the power switch on the bottom of the device to the ON position. The lenses will briefly illuminate amber to indicate that the device is on. This is the time to put both headphone earbuds in your ears, put the device on and prepare for the 16-minute therapy.

Refer to the instructions below to start the session using the Sana Relief app.

At the end of therapy, the light and sound will turn off. You can turn the device off at any time by sliding the power switch to the OFF position.





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## CONNECTING TO THE APP

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The first step to set up your app is to download it; the Sana Relief App can be downloaded for Android from the Play Store app, and iOS devices from the Apple Store app. Once downloaded access the app from you home screen.

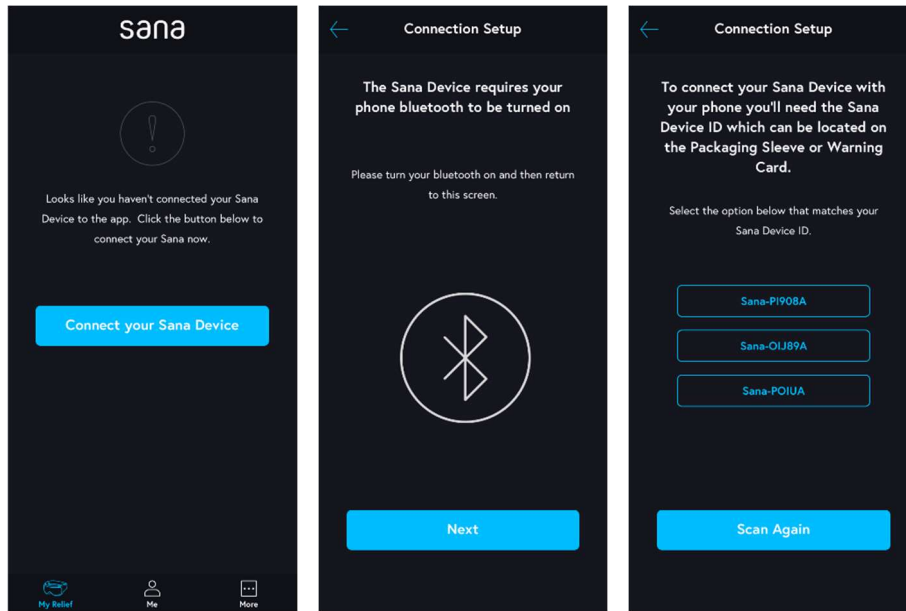
In order to use the Sana Relief App for the first time, you must create a Sana account. Select the “Sign Up” option from the screen and complete with the required information. After completing this step, make sure to verify your account with the code sent to the email you provided.

Two screenshots of the Sana app interface. The left screenshot shows the 'Sign Up' screen with fields for Email (johnsmith@example.com), Age (Minimum age is 18), Password, and Confirm Password. The right screenshot shows the 'Email Validation' screen with a message about a validation code and a field for the code (A9P9123).

After setting up your account, the app will guide you through 4 more set up steps, which will help you understand further your Sana Device.



The first step to use your Sana Device is to connect it to the App. On the Home screen, select the “Connect to your Sana Device” Option. Make sure that the Mask is charged (see Charging section) and that the Bluetooth is enabled on your phone. Follow the direction from the app to connect.



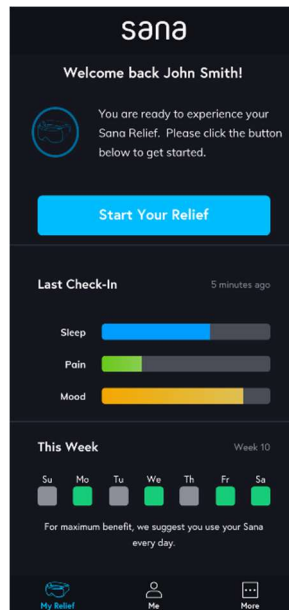
Address 130 Miners Drive, Suite 101  
Lafayette, CO 80026  
United States

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IFU Document # PRT-0081  
Released: May 13, 2020

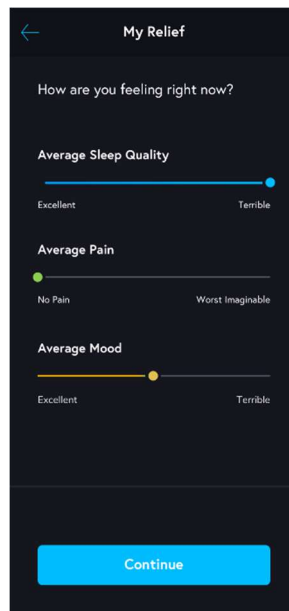
info@sana.io Email  
www.sana.io Web

## STARTING THE DEVICE WITH THE APP

Once the Sana Device is connected to the My Relief App, you are ready to start your relief. Select the “Start your Relief” option on your “My Relief” tab.

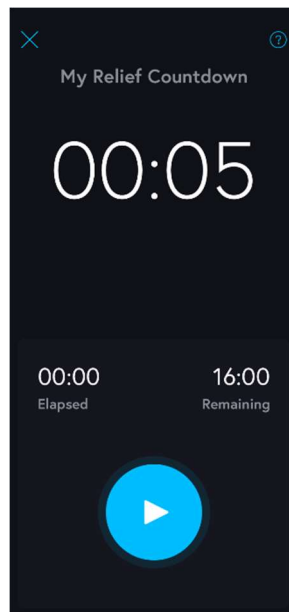


Once prompted, add your current Sleep, Pain and Mood state (optional) and click continue.

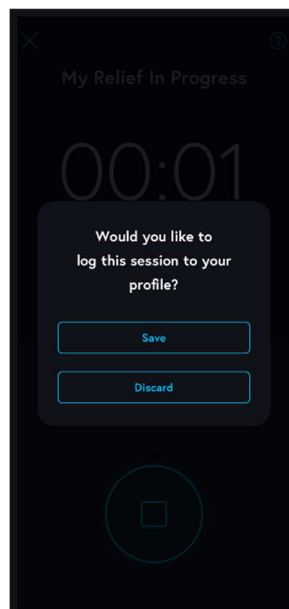




You will see the Relief screen, place your Sana Device and headphones as explained on previous steps. When ready, Click the Play button, you will have 5 seconds to place the Sana Device in position to start the session.



You can stop the session at any point by clicking the STOP symbol on the screen. If you decide to Stop mid session, or at the end of the session, you will have the option to save or discard the session. It is recommended to save the session to see your progress over time.



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## ADJUSTING FIT

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The Sana device should be comfortable to wear. Please get into your chosen location for therapy and put the device on. Adjust the strap and position so the device fits snugly but comfortably to your face and shuts out the majority of ambient light. The device does not need to be so tight to cause discomfort but should feel snug and secure. You should remove eye-glasses and other bulky headwear prior to using the device. We recommend you connect the headphones to the device before you turn it on. Please also take the time to fit the headphones for your comfort. You can use the ones supplied or your own. Most headphones, including the ones supplied, come with a range of earbud sizes and means of adjustment so you can adjust the fit to be most comfortable.

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## ADJUSTING BRIGHTNESS

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The device works best when your eyes are closed and you can see light through your closed eyes. The minimum level should be such that you can see the light levels change when you have your eyes closed, the maximum is whatever is still comfortable, adjust to what feels comfortable and good to you, some people like it just visible through closed eyes, some people like it super bright (especially when in pain) so test at different levels and see what feels best to you.



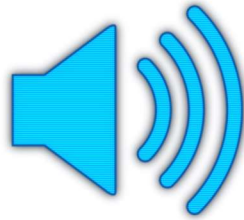
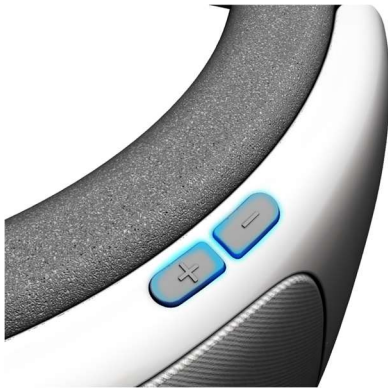
To adjust the light level, use the buttons on the top of the device. You will find them with your right hand when you are wearing the device. The button nearest your ear turns the brightness down, the one nearest the center of your forehead turns the brightness up. Press and hold to adjust light level quickly. Press and release for fine adjustment.

Feel free to adjust the light levels between sessions, and within sessions to be comfortable. For example, you will likely need a lower light level setting at night than in the middle of the day.

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## ADJUSTING VOLUME

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When using the Sana device, you should connect your headphones to the audio-jack located on the bottom of the device near the charging port. You can use the headphones supplied or your own. The volume should be loud enough for you to clearly hear the supplied tones but should not be so loud to be uncomfortable.

To adjust the sound level, use the buttons on the top of the device. You will find them with your left hand when you are wearing the device. The button nearest your ear turns the volume down, the one nearest the center of your forehead turns the volume up. Press and hold to adjust volume level quickly. Press and release for fine

adjustment.

**CAUTION:** Use both headphone earbuds for maximum therapeutic effect

**NOTE:** Some headphones are labelled for Left (L) and Right (R) ears; be sure to place correct earbuds in correct ears for best results

**CAUTION:** To prevent possible hearing damage, do not listen at high volume levels for long periods.



We recommend using noise cancelling headphones, but they are not essential. Most noise cancelling headphones will need to be re-charged when not in use.

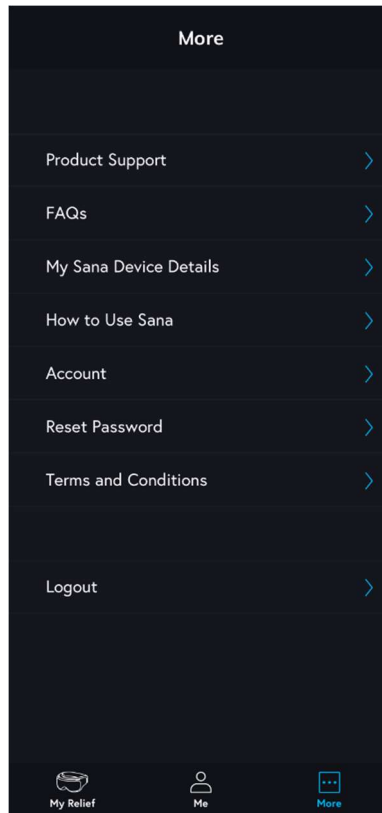


## OTHER FEATURES OF THE APP

The My Relief App comes with various functionalities to help you track your progress and understand more about your Sana Device. The first and main source of information about your progress can be found on your “Me” tab. By clicking here, you will see details of your daily usage, your Sleep, Mood and Pain average over time, and a graphic representation of the changes of your sleep, mood and pain.



For more information you can always access your “More” tab. In here you can learn more about your Sana Device, contact our support team with any questions or problems, see the instructional video on how to use your device, and modify any account and password information.



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## CLEANING

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As needed, the hard plastic parts of the Sana device may be cleaned with a soft cloth dampened with water. Do not use cleaning wipes, cleaning chemicals or excessive water. Use only water. Take care not to use any abrasive material especially on the lenses of the device to avoid scratching.



### CAUTION: Keep Dry

As needed, the foam part that sits against the face may be carefully removed from the device for cleaning. It is held onto the device using Velcro fastening, and may be simply peeled off the inside of the device. Once removed, the foam may be gently hand washed with water. Hand-wash detergent may be used if needed but should be fully and thoroughly rinsed from the foam. Do not use excess water; avoid fully soaking the foam part. Press the foam part between absorbent surfaces (such as a towel) to remove excess water after cleaning and lie flat to air dry fully before being re-fitted to the device.

- Only use the foam provided with the device
- Do not use the device without the foam fitted
- Do not use harsh cleaning chemicals to wash the foam, use only a very small amount of hand-wash laundry detergent and rinse the foam thoroughly. Do not use detergents known to irritate your skin. Do not use dish soap
- **Do not machine wash or tumble dry**
- Do not fully saturate during washing of foam; use water sparingly and press excess water from foam into absorbent material. Do not wring or mis-shape during washing or drying.
- **Do not re-fit the foam to the device or use the foam until fully dry.** Damp foam can damage the device and cause irritation.

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## STORAGE AND TRANSPORT

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When not in use or charging, the Sana device and its accessories should be stored in the reusable case provided. Keep device and accessories out of reach of children and pets. Disconnect headphones prior to storage to avoid damaging the device. We recommend you keep the device charged so it has sufficient battery life for therapy when you need it; please refer to section “charging” on p8.

The case is appropriate both for storage and transport of the device, including for air travel. For international use, a power adaptor may be required to allow re-charging of the device, headphones and tablet. Use of the device does not change when used outside the home or clinic environment; use of the device during extended travel, such as on a plane flight, is appropriate. Do not use the device while driving.

Storage and Transport Conditions:

Temperature	-25°C to +70°C
Relative Humidity	Up to 90%, non-condensing
Atmospheric pressure	700 hPa to 1060 hPa

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## FAULT CONDITIONS

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If a fault is detected when the device is switched on, the device lenses will flash blue continuously. If this happens, turn the device off, wait a few seconds and turn the device back on. If the fault continues, recharge the device (see “charging” on p8) and turn the device on. If the fault continues, contact your physician for a replacement immediately. The device will be returned to Sana for investigation and repair. There are no known faults that can cause you harm.

**CAUTION:** Do not disassemble the device



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## DEVICE RETURN & DISPOSAL

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The device is expected to operate reliably for a minimum of 18 months. Should you experience device failure prior to this, please contact Sana Customer Success at 720-310-3370 to arrange for device return and replacement. The device may continue to function longer than this and can continue to be safely used.

Should you need to dispose of the device locally; please note that this product contains a rechargeable lithium ion battery. At the end of device life, dispose of device in regular waste or according to local regulation for the disposal of lithium ion batteries. Discharge battery prior to disposal. Do not dispose of device in fire or heat.

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## ADDITIONAL INFORMATION

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In 1992, Richard Hanbury, the now-CEO of Sana Health, suffered a near-fatal car crash in Yemen, which left him paralyzed. 14-months later he was given less than 5 years to live due to severe chronic nerve pain that was debilitating both recovery and sleep quality.

Richard experienced by chance the “flow state” effect whilst in hospital and has since devoted some 24-years to researching, developing and optimizing the algorithms that reliably recreate this “flow state”. This is the technology built into the Sana device and has been developed in conjunction with multiple pain management facilities, sleep management facilities, military organizations and elite sports teams.

During development the Sana device has been used by over 1,300 users. No device related adverse events have been reported. Sana is engaged in clinical trials to investigate use of the device for various conditions. This work is ongoing. The Sana Device is not FDA approved for use in the treatment of any clinical condition, and is intended only for use in the management of rest and recovery in healthy individuals at this time. Please refer to the website for up to date information on recent clinical studies ([www.sana.io](http://www.sana.io)).

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## HOW IT WORKS

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The Sana device is a non-addictive simple mask and headphones you wear on your head. The device uses audio visual stimulation to increase balance between the left and right side of your brain leading to greater relaxation.

In the early 1930s, light and sound stimulation were reported to change the rhythm of brain activity, termed “entrainment”. Brain activity can be tracked through brainwaves, which represent the electrical firing of the neurons of the central nervous system and can be measured by electroencephalogram (EEG). It is through these electrical signals that the brain communicates within itself and with other organ systems.

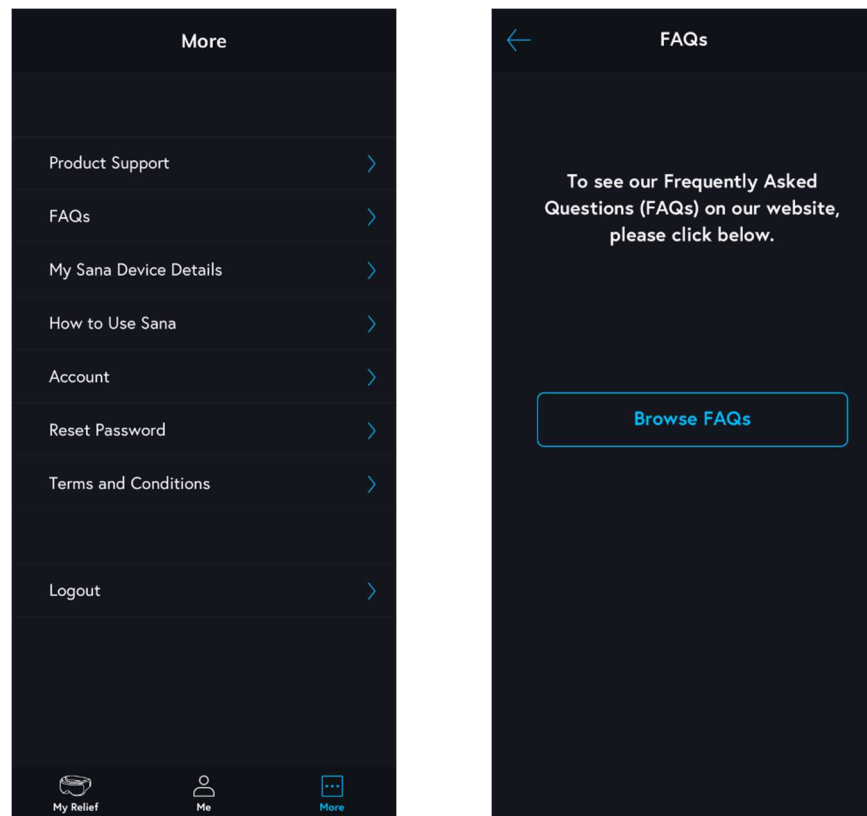
- Delta activity (0.5–3Hz) is dominant primarily during deep sleep
- Theta activity (4–7Hz) is typically seen in drowsy and relaxed states

- Low alpha (8–10Hz) is the dominant brainwave bandwidth observed during meditation and the state of turning inward (daydreams, dissociation from external stimulation)

Ongoing use of your Sana device resembles the effect of long-term meditative practices which leads to a more restful state overall. Sana can clear a busy mind and accelerate mental and physical recovery.

## FREQUENTLY ASKED QUESTIONS

Frequently asked questions and a reminder of the operating instructions in this document can be found on the FAQs option under the “More” Tab of the app or by visiting the Sana website at: <https://www.sana.io/faqs>



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## MANUFACTURING INFORMATION

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Manufactured for:  
Sana Health Inc.  
130 Miners Drive Suite 101  
Lafayette CO 80026

Date of manufacture per product label and pack insert



Device serial number can be found on the package label, the pack insert and on the device under the foam part. For instructions on removal of the foam part, see “cleaning” on p14.



For more information, contact Sana Health:  
[info@sana.io](mailto:info@sana.io)

eIFU document number: PRT-0081 Revision 01 dated May 13, 2020  
\*Date reflects authoring date, controlled copy per Sana Health Quality Management System, effective date per system release.

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## TECHNICAL INFORMATION

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Model: Sana Beta

Per IEC 60601-1:2005 Ed. 3 + A1; C1:2014, the Sana device in its entirety is considered a Type BF applied part.



Ingress protection **IP21**

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## ELECTROMAGNETIC COMPATIBILITY

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The Sana device conforms to IEC 60601-1-2:2014 for immunity and emissions, however special precautions regarding EMC (Electro Magnetic Compatibility) should be taken according to the information provided below.

- The use of accessories and cables other than those provided with the devices may result in increased emission or decreased immunity of the device and result in improper operation.





- Use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the device and other equipment should be observed to verify they are operating normally.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Sana device Beta Device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Guidance and Manufacturer's Declaration - Emissions		
The Sana device is intended for use in the electromagnetic environment specified below. The customer or user of the Sana device should ensure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The Sana device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	
Harmonics IEC 61000-3-2	Complies	The Sana device is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Flicker IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Immunity			
The Sana device is intended for use in the electromagnetic environment specified below. The customer or user of the Sana device should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
ESD IEC 61000-4-2	±8kV Contact ±15kV Air	±8kV Contact ±15kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%
EFT IEC 61000-4-4	±2kV Mains ±1kV I/O's	±2kV Mains N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout IEC 61000-4-11	>95% Dip for 0.5 Cycle  >95% Dip for 1 Cycle  30% Dip for 25/30 Cycles  >95% Dip for 250/300 Cycles	>95% Dip for 0.5 Cycle  >95% Dip for 1 Cycle  30% Dip for 25/30 Cycles  >95% Dip for 250/300 Cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Sana device requires continued operation during power mains interruptions, it is recommended that the Sana device be powered from an uninterruptible power supply or a battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	30 A/m	30A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration - Immunity	
The Sana device is intended for use in the electromagnetic environment specified below. The customer or user of the Sana device should ensure that it is used in such an environment.	

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 V 0.15 MHz-80 MHz 6 V1) in ISM between 0.15 MHz and 80 MHz2 80 % AM at 1 kHz	3 V 0.15 MHz-80 MHz 6 V1) in ISM and amateur bands between 0.15 MHz – 80 MHz2	HOME HEALTHCARE FACILITY ENVIRONMENT
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	HOME HEALTHCARE FACILITY ENVIRONMENT

1) r.m.s. before modulation is applied.

2) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

Guidance and Manufacturer's Declaration – Immunity to RF wireless communication equipment						
The Sana device is intended for use in the electromagnetic environment specified below. The customer or user of the Sana device should ensure that it is used in such an environment.						
Test Frequency	Band <sup>1</sup>	Service <sup>1</sup>	Modulation <sup>2</sup>	Maximum Power	Distance	Immunity Test Levels
MHz	MHz			W	Meters	(V/m)
385	380 - 390	TETRA 400	Pulse modulation <sup>2</sup> 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM <sup>3</sup> ± 5 kHz deviation 1 kHz sine	2	0.3	450
710 745 780	704 - 787	LTE Band 13, 17	Pulse modulation <sup>2</sup> 217 Hz	0.2	0.3	9
810 870 930	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation <sup>2</sup> 18 Hz	2	0.3	28
1720 1845 1970	1700 - 1900	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation <sup>2</sup> 217 Hz	2	0.3	28
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation <sup>2</sup> 217 Hz	2	0.3	28
5240 5500 5785	5100 - 5800	WLAN 802.11a/n	Pulse modulation <sup>2</sup> 217 Hz	0.2	0.3	9
NOTE If necessary, to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.						

Guidance and Manufacturer's Declaration – Immunity to RF wireless communication equipment
The Sana device is intended for use in the electromagnetic environment specified below. The customer or user of the Sana device should ensure that it is used in such an environment.
<sup>1</sup> For some services, only the uplink frequencies are included.
<sup>2</sup> The carrier shall be modulated using a 50 % duty cycle square wave signal.
<sup>3</sup> As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

## REGULATORY NOTICES



This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Any changes or modifications not expressly approved by Sana Health, Inc could void the user's authority to operate the device.

## DEFINITION OF SYMBOLS



Caution

Per ISO15223-1:2016(E)



Keep Dry

Per ISO15223-1:2016(E)



Possible Hearing Damage

EN 50332-1:2013



Manufacturer

Per ISO15223-1:2016(E)



Serial Number

Per ISO15223-1:2016(E)



Consult Instructions For Use

Per ISO15223-1:2016(E)



Applied Part Type BF

Per IEC 60601-1:2005 Ed. 3  
+ A1; C1:2014

## IP21

Ingress Protection rating 21 for solid particles >12.5mm diameter and dripping water

Per IEC 60601-1:2005 Ed. 3  
+ A1; C1:2014



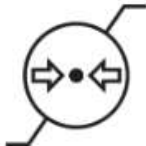
Temperature Limit

Per ISO15223-1:2016(E)



Humidity Limitation

Per ISO15223-1:2016(E)



Atmospheric Pressure Limitation

Per ISO15223-

1:2016(E)

## REFERENCES

- ISO-15223-1; Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied —Part 1: General requirements" Corrected version 2017-03
- ISO 15223-2, Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation
- FDA guidance on Medical Device Labeling; Final guidance for Industry and FDA reviewers, Document issued April 19, 2001
- Sana Health Quality Manual, Document QM-001 (available on request)
- "The Sana Device: A Non-Invasive Treatment for Pain", R. Hanbury, MBA, Sana Health Founder and Sana Device Inventor, 2019
- EN 50332-1:2013: Sound system equipment: Headphones and earphones associated with personal music players - Maximum sound pressure level measurement methodology - Part 1: General method for "one package equipment"
- IEC 60601-1:2005 Ed. 3 + A1; C1:2014 Medical electrical equipment—Part 1: General requirements for basic safety and essential performance