INSTRUCTIONS FOR USE

APP-ENABLED DEVICE

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PURPOSE OF THIS DOCUMENT

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.

INTENDED USE

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. Through clinical studies, the Sana device may be used for exploring management of such conditions and symptoms associated with Fibromyalgia, Neuropathic Pain, PTSD, Anxiety, and Depression. This includes symptoms such as severe pain, fatigue, and reduced sleep quality. The device is not approved for use in the management of these conditions unless you are a part of a controlled study.

DEVICE DESCRIPTION

The Sana device is a mask that is worn on your face, similar to a transitional sleep mask.

The Sana device delivers very gentle coordinated pulses of light (through closed eyelids) and sound (through headphones) that encourage you into a “flow state” where the activity in the left and right sides of your brain are balanced, generating natural relaxation and reducing your pain.

The underlying mechanism of action for the Sana device is Audio Visual Stimulation (AVS), a form of neurofeedback. This non-pharmacological intervention that has been used for both performance enhancement and pain symptom 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 therapy session, 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.

PACK CONTENTS

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 set of headphones with standard plug-in jack. You may use your own headphones or the ones supplied. Cordless (Bluetooth) headphones cannot be used.
    - In-ear (earbuds) or over-ear type are both acceptable; please use what is most comfortable
    - We recommend use of ANC, but it not required
- One information card

You will also need the following items to be able to use the Sana:

- Download the Sana App from Google Play (Android) or iTunes Store (Apple) and register your account for full benefit.

CONTRAINDICATIONS

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
- Persons sensitive to light
- Persons with a history or presence of condition(s) that may affect balance, such as seizure disorders, tinnitus or vertigo
- Persons suffering from migraine headaches
- 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.

GENERAL WARNINGS AND PRECAUTIONS

- 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.

INTENDED USERS

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This may include such uses as:

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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 medication condition. Through clinical studies, it can be used by people who have Fibromyalgia, Neuropathic Pain, PTSD, Anxiety, and Depression and wish to use a device to help them manage their symptoms. This includes severe pain, fatigue, and reduced sleep quality. The device is not approved for use in the management of these conditions unless you are part of a controlled study. The Sana device may be used in conjunction with your other medications and treatments.

RISKS AND BENEFITS

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 your doctor.

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 therapy session to end.

During a therapy session, you should expect to see pulses of amber light through your closed eyelids and hear pulses of sound through the headphones - you may use the ones supplied or your own. The speed, patterns and sequence of these pulses of light and sound will vary through the therapy session. The therapy session starts relatively fast and then progressively slows through the duration of the session..

Some people find relief on first use, while others require up to 5 therapy sessions 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 your doctor 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 your doctor.

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 below levels that are normally considered safe to 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 using systems required by the FDA to ensure the product is safe.

PROPER USE AND USE SITUATIONS FOR THE DEVICE

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 eyeglasses 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.

You may use the device as often as you like. We recommend that you use the device any time you feel in pain; especially when you feel your pain starting to get worse. If you find you are in pain first thing in the morning, using the device may help.

The device also helps relax you towards sleep. Sleep is very important in the healing process. 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.

EXPECTED OUTCOMES FROM USE OF THE DEVICE

You should see benefit within the first few uses of the device. The effects may last longer and be more effective in reducing your pain, anxiety and fatigue over time, so continued and regular use of the device is important. We recommend 1-2 uses per day as part of your care routine, more as needed.

You may also notice the device helps you sleep better, so you should be sure to use the device in bed immediately before going to sleep.

OPERATING INSTRUCTIONS

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

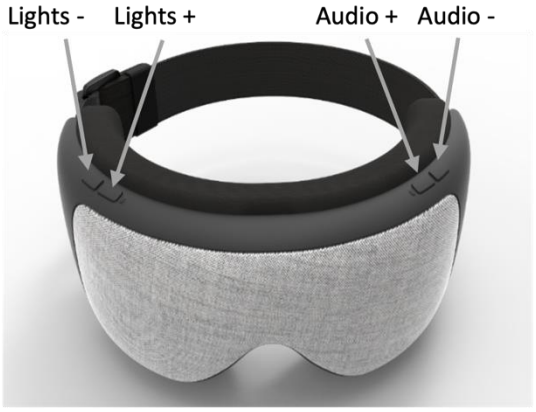
www.sana.io/instructions-sana-device-with-app

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 

Overall Layout of the Sana Device



See the following sections for further details: First Use, Turning On/Off, Adjusting Brightness, Adjusting Volume

FIRST USE

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 headphone 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 charger(s) (and the headphones you want to use) in the case with the device so they don't get lost.

ADJUSTING FIT

Pull to tighten

The Sana device should be comfortable to wear. Please get into your chosen location for a therapy session 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 eyeglasses and other bulky headwear prior to using the device. We recommend you connect your 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.

CHARGING

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 the supplied charger to charge the 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.

To prolong the life of your Sana device battery:

- Switch the power to the “OFF” position after a therapy session is complete and not in use.
    - If you fall asleep with the device on, remember to switch it off when you wake up.
- Keep the device at room temperature in a dry location. Overheating can damage the battery.
- Do not allow your battery to run out fully – charge it after every 6-8 therapy sessions.
- Use the charger that came with your device – this will provide optimal charging.

TURNING ON / OFF

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 illuminate amber for approximately 1-second to indicate that the device is on. This is the time to put the headphone earbuds in your ears, put the device on and prepare for the therapy session.

The lenses will then briefly turn off and the therapy session will start once a session start has been triggered by the app. Refer to the instructions below to start the therapy session using the Sana Relief app.

At the end of the therapy session, 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.

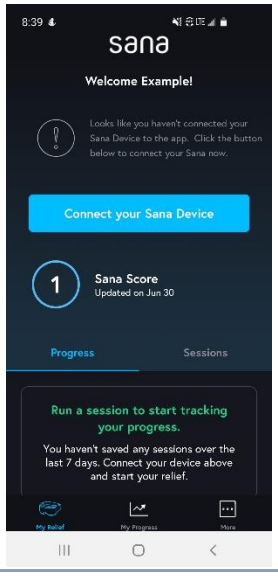
If the device has insufficient battery charge for a therapy session, the lens will flash blue briefly and then turn off. In this case, charge the device (see “Charging” on p8) before use.

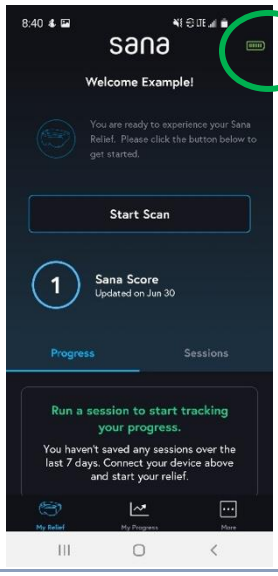
CONNECTING TO THE APP

When you first download the Sana device App, the app will ask you to pair with your device using the instructions provided on the screen. This needs to be completed before the App can work with your Sana. Select “Connect your Sana Device” with your Bluetooth on and follow the prompts to connect your device.

When you open the app to start a therapy session, the device will connect to the app automatically. Be sure the device is switched on when you open the app. If the device does not connect to the app right away, make sure the device is switched on and then attempt to connect by clicking ”Start Scan”. When your device is connected to the app, your current battery status of the Sana device will show in the top right-hand corner.

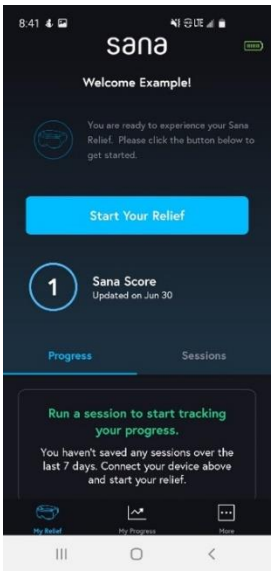
If the device has insufficient battery charge for a therapy session, a warning message will appear in the app when you attempt to run a therapy session. In this case, charge the device (see “Charging” on p8) before use.



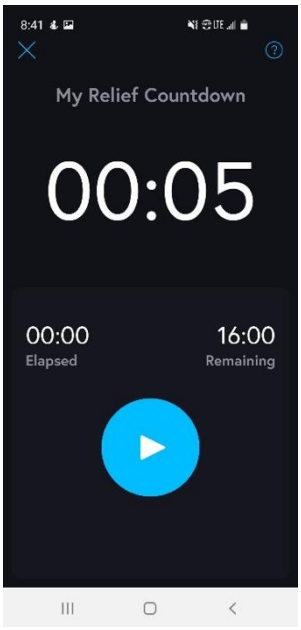


STARTING THE DEVICE WITH THE APP

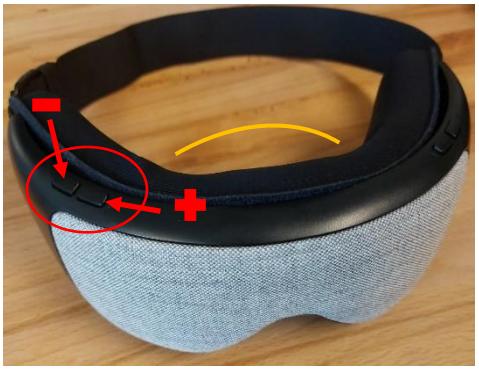
Once you have connected the device and selected the “Start Scan” button, you will then be allowed to “Start Your Relief”.



Once “Start Your Relief” was selected, you will be asked to rate your current pain, mood, and sleep (see “Other Features of the App” on page 13), followed by a 5 second countdown to put the device on, before the therapy session starts. You can start the countdown when you are ready and pause the countdown if you need more time.



ADJUSTING BRIGHTNESS



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 prefer the light to be just visible through closed eyes, some people prefer the light to be very 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 button to adjust light level quickly. Press and release button for fine adjustment.

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

ADJUSTING VOLUME

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 button to adjust volume level quickly. Press and release button for fine adjustment.

CAUTION: Use both headphone earbuds for maximum therapeutic effect

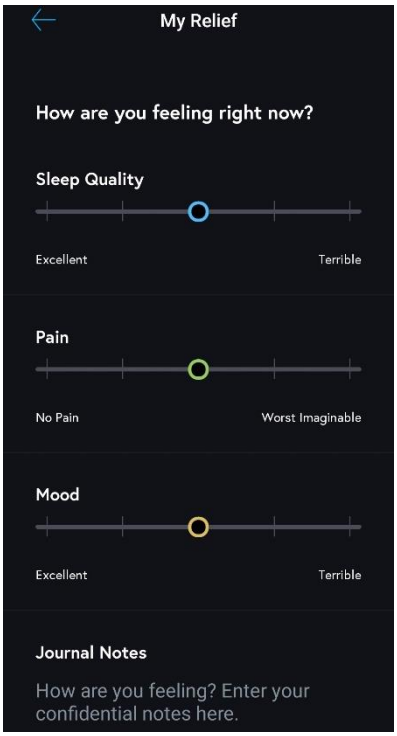
NOTE: Some headphones are labeled for Left (L) and Right (R) ears, be sure to place correct earbuds in correct ears for best result.

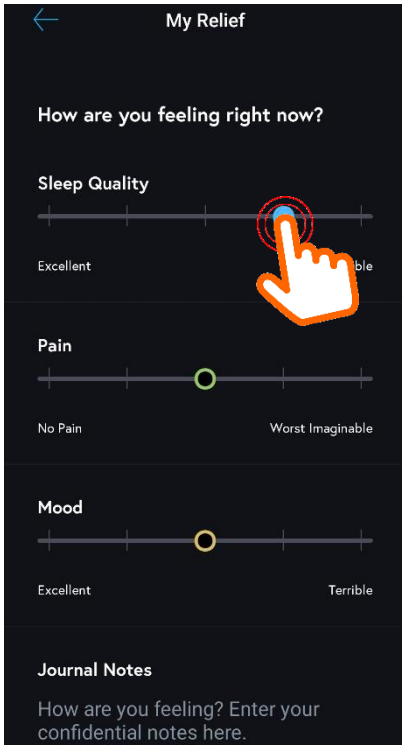
CAUTION: To prevent possible hearing damage, do not listen at high volume levels for long periods.

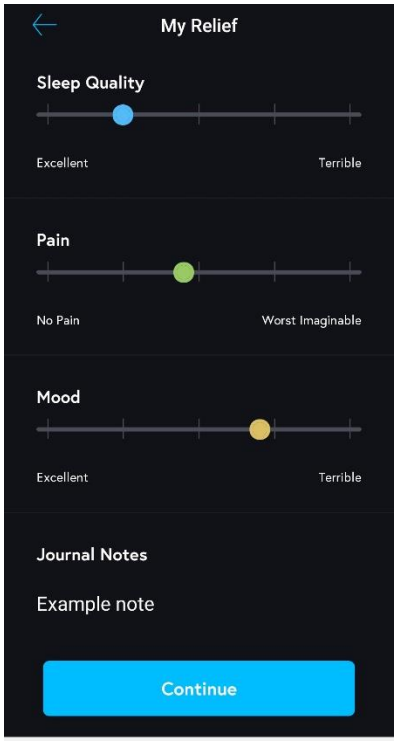
We recommend using noise cancelling headphones, but they are not essential. Most noise cancelling headphones will need to be re-charged when not in use.

OTHER FEATURES OF THE APP

Before a therapy session (see “Starting The Device with the App”, p10), you will be asked to rate your pain, mood, and sleep on a scale between “no pain felt” and “worst pain imaginable”. Simply touch your finger to the screen in the location that best represents how you are feeling at that moment.







A dot will appear on the line where you selected. There is also a section for optional Journal Notes to keep track of any additional thoughts. If you feel this is a good representation of how you are feeling, press “continue”.

CLEANING

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 the foam**
- 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.

STORAGE AND TRANSPORT

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 sessions 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

FAULT CONDITIONS

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

DEVICE RETURN & DISPOSAL

The device is expected to operate reliably for a minimum of 18 months. Should you experience device failure prior to this, please contact Sana 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.

ADDITIONAL INFORMATION

In 1992, Richard Hanbury, the now-CEO of Sana Health, suffered a near-fatal car crash in Yemen, which left him paralyzed. Fourteen 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 Health have recently completed a study into the use of the Sana Device in patients with fibromyalgia.

- 84% of patients saw benefit (reduction in pain)
- Patients with highest pain levels before the start of the trial saw most benefit from use of the device

In a population with severe symptoms, the device gave relief on a number of parameters that, when considered as a whole, were seen as clinically valuable to the majority of patients. Eighty-five percent of patients wished to continue using the Sana device at the end of the trial.

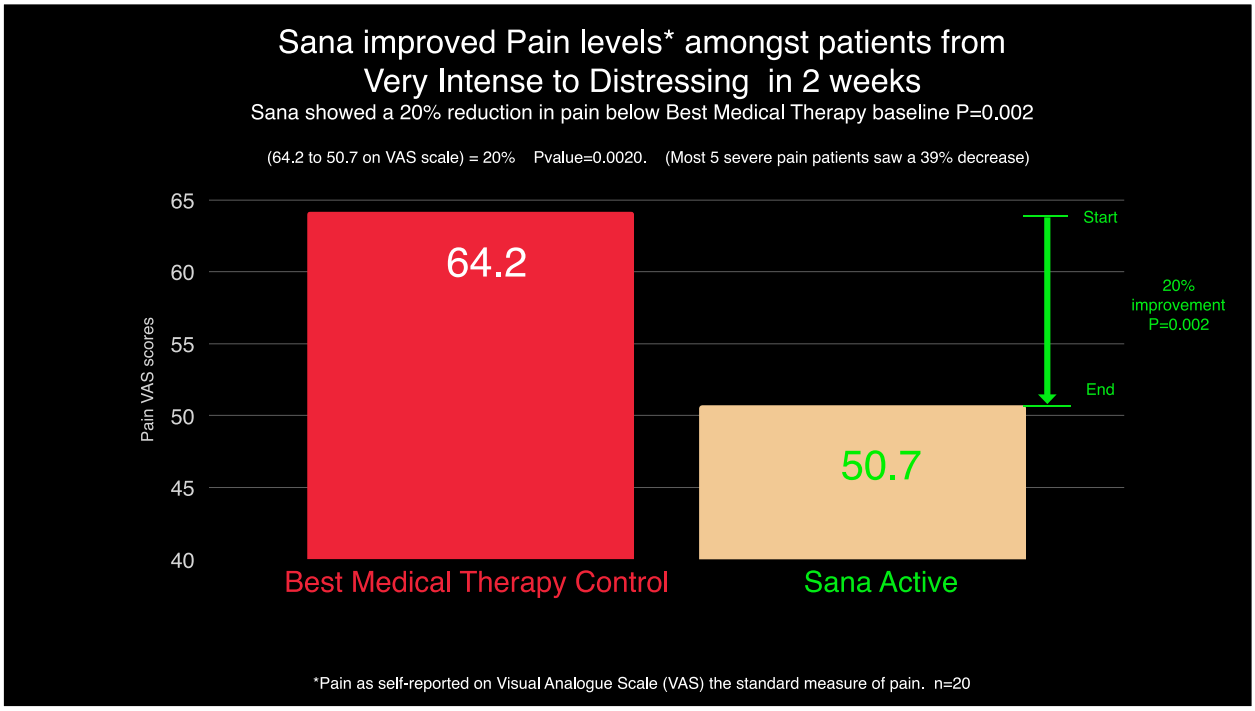
- The change in average pain at the start of the trial compared to average pain at the end of the trial was reduced by 19.6%
- 47% of patients experiences a change of greater than 10 points on a 100-point scale, with a mean reduction of 36.4%
- 32% of patients experienced a change of greater than 30%, with a mean reduction of 42.7%.
- All patients presented a reduction in average post-use pain compared to pre-use pain

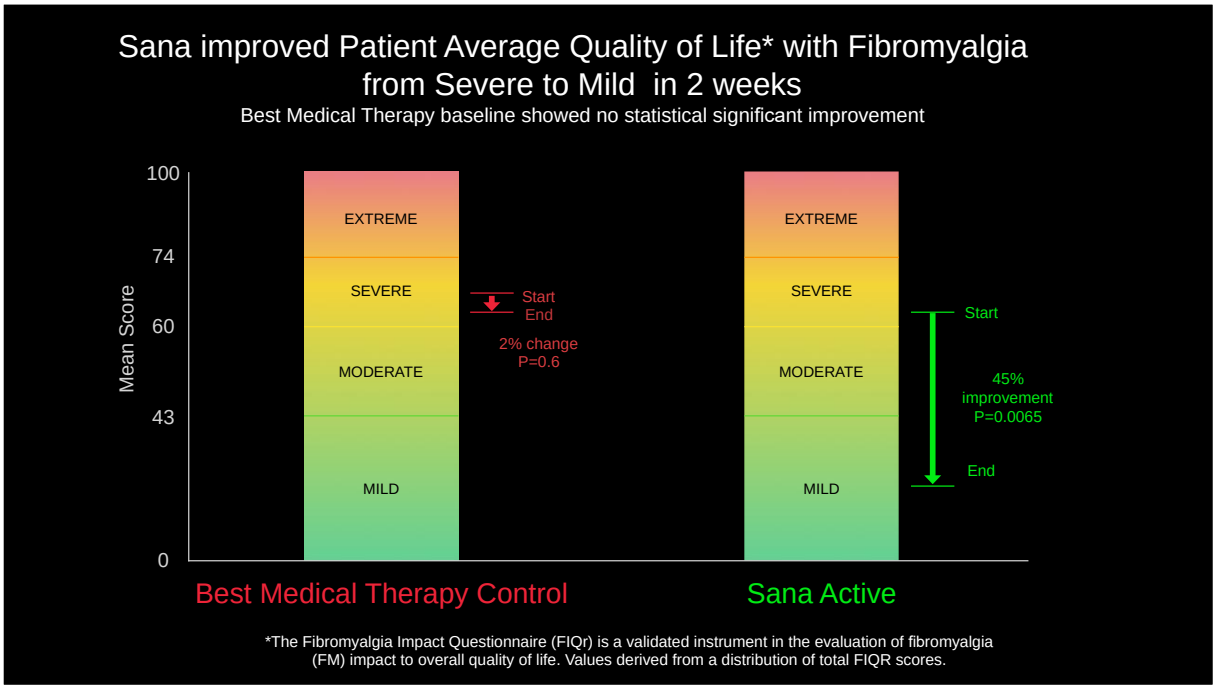
The data supports confirmation of a statically significant reduction in pain levels

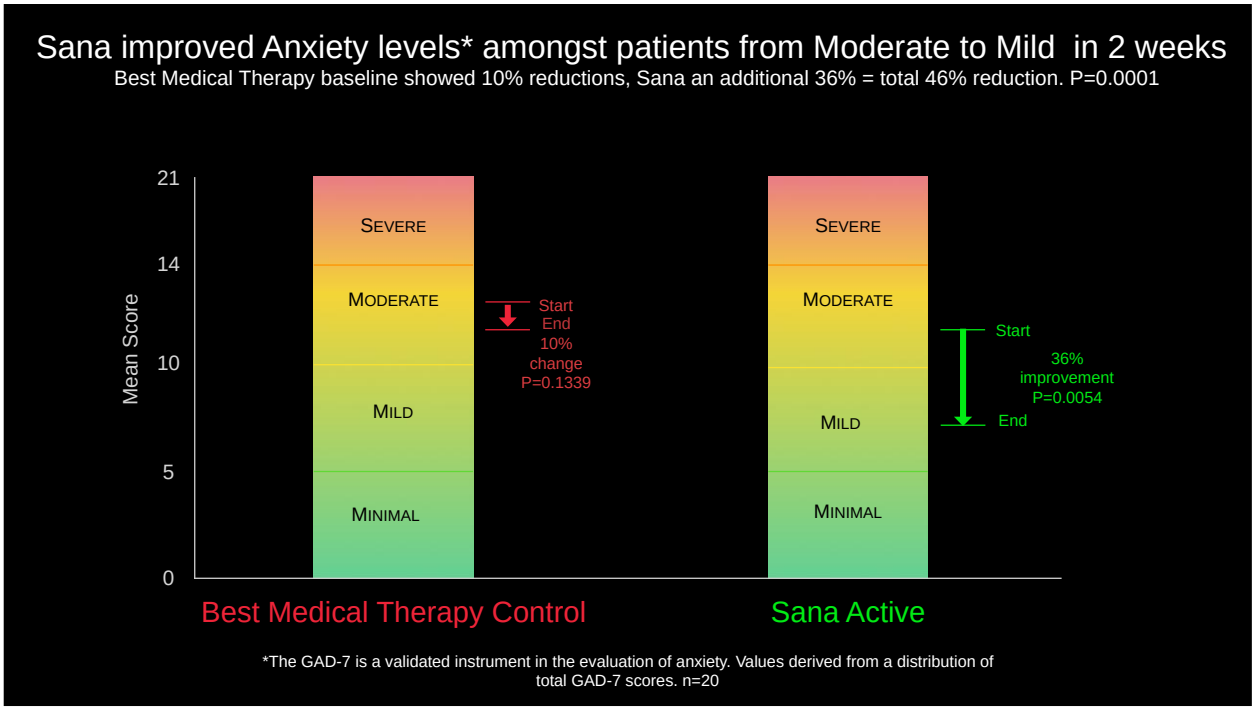
Statistically significant benefit was found within the patient population on

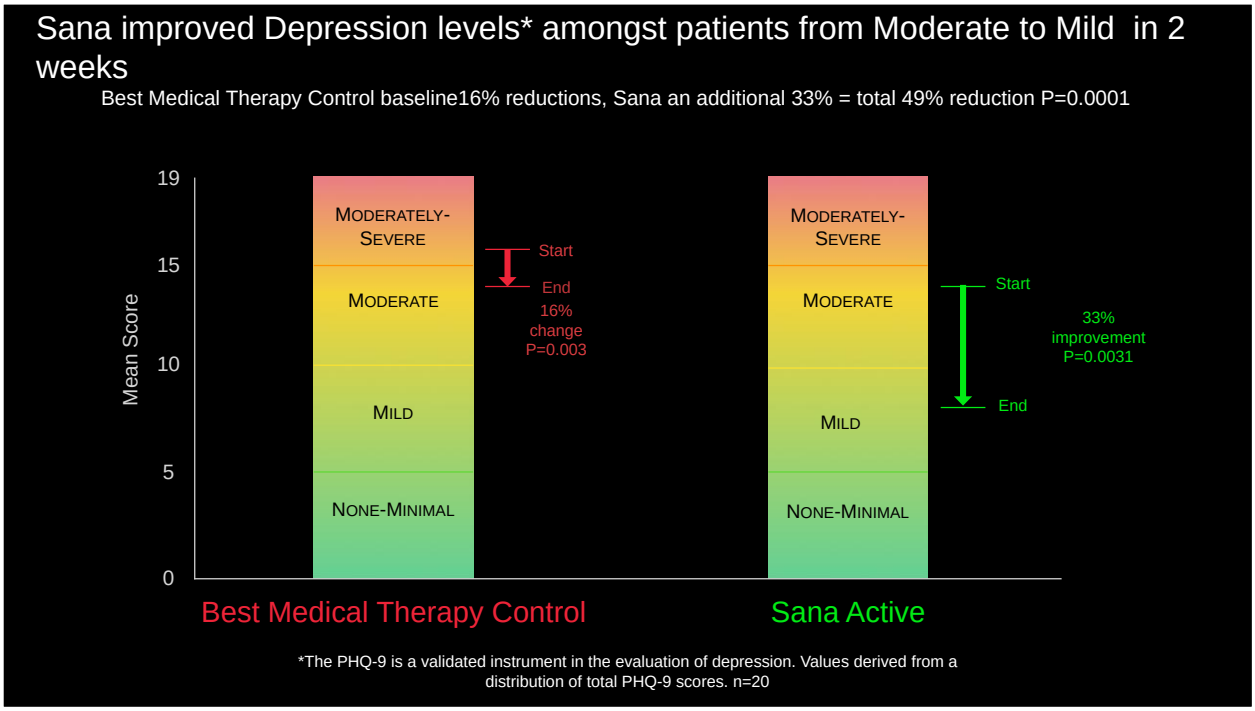
- Improved sleep quality (55% of patients)
- Reduced anxiety (75% of patients)
- Reduced depression (75% of patients)
- Reduced impact of fibromyalgia on quality of life (70% of patients)

These effects are shown on the graphs below:




Sana improved Patient Average Quality of Life* with Fibromyalgia from Severe to Mild in 2 weeks
Best Medical Therapy baseline showed no statistical significant improvement
Mean Score
100
74
60
43
0
EXTREME
SEVERE
MODERATE
MILD
Start
End
2% change
P=0.6
45% improvement
P=0.0065
Best Medical Therapy Control
Sana Active
*The Fibromyalgia Impact Questionnaire (FIQr) is a validated instrument in the evaluation of fibromyalgia (FM) impact to overall quality of life. Values derived from a distribution of total FIQR scores.


Sana improved Anxiety levels* amongst patients from Moderate to Mild in 2 weeks
Best Medical Therapy baseline showed 10% reductions, Sana an additional 36% = total 46% reduction. P=0.0001
Mean Score
21
14
10
5
0
SEVERE
MODERATE
MILD
MINIMAL
Start
End
10% change
P=0.1339
36% improvement
P=0.0054
Best Medical Therapy Control
Sana Active
*The GAD-7 is a validated instrument in the evaluation of anxiety. Values derived from a distribution of total GAD-7 scores. n=20



There were no serious adverse events, device related or otherwise reported in the trial. Some mild adverse events were reported that may or may not be related to use of the Sana device, including headache, visions of past trauma, restlessness, anxiety, insomnia, migraine, nausea and light sensitivity. All resolved when the patient stopped using the device at that time, and all patients were able to continue use of the device the next day.

A number of additional clinical trials are ongoing and will be subject to FDA review in due course for new uses of the Sana. Please refer to the website for up-to-date information on recent clinical studies (www.sana.io).

HOW IT WORKS

The Sana device delivers very gentle coordinated pulses of light (through closed eyelids) and sound (through headphones) that encourage you into a “flow state” where the activity in the left and right sides of your brain are balanced, generating natural relaxation.

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

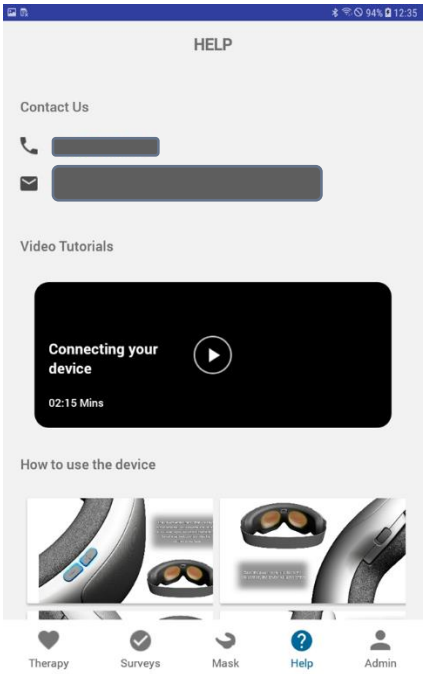
In the early 1930s, light and sound stimulation were reported to change the rhythm of brain activity, termed “entrainment”. Brain activity can be tracked through brainwaves, which represent the electrical firing of the neurons of the central nervous system and can be measured by electroencephalogram (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

The AVS of the Sana device resembles the effect of long-term meditative practices by eliciting EEG signatures similar to those achieved during meditation. In particular, the AVS inputs induce the brain to synchronize its electrophysiological patterns, leading to a restful state. The EEG signatures in this restful state are associated with reductions in perceived pain, depression, anxiety, insomnia.

FREQUENTLY ASKED QUESTIONS

Frequently asked questions and a reminder of the operating instructions in this document can be found on the HELP tab of the app or by visiting the Sana website at: https://www.sana.io/faqs



MANUFACTURING INFORMATION

Manufactured for:
Sana Health Inc.
2051 Dogwood St., Suite 220
Louisville, CO 80027USA

Date of manufacture per product label and pack insert

Kiddly Marketing & Fulfillment
31 Successful Way
Dawsonville, GA 30534 USA

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 p13.

For more information, contact Sana Health:
info@sana.io

eIFU document number: PRT-0051, Revision 08 dated 2022-04-28*
*Date reflects authoring date, controlled copy per Sana Health Quality Management System, effective date per system release.

TECHNICAL INFORMATION

Model #: Beta Mk 4

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**

ELECTROMAGNETIC COMPATIBILITY

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, 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.

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.			
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 MHz[2]	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 [1]**	**Service [1]**	**Modulation [2]**	**Maximum Power**	**Distance**	**Immunity Test Levels**
MHz	**MHz**			**W**	**Meters**	**(V/m)**
385	380 - 390	TETRA 400	Pulse modulation [2] 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM [3] ± 5 kHz deviation 1 kHz sine	2	0.3	450
710 745 780	704 - 787	LTE Band 13, 17	Pulse modulation [2] 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 [2] 18 Hz	2	0.3	28

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.						
1720 1845 1970	1700 - 1900	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [2] 217 Hz	2	0.3	28
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [2] 217 Hz	2	0.3	28
5240 5500 5785	5100 - 5800	WLAN 802.11a/n	Pulse modulation [2] 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.						
[1] For some services, only the uplink frequencies are included.						
[2] The carrier shall be modulated using a 50 % duty cycle square wave signal.						
[3] 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

FEDERAL COMMUNICATIONS COMMISSION

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.

INNOVATION, SCIENCE AND ECONOMIC DEVELOPMENT CANADA

This device contains license-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's license-exempt RSS(s). Operation is subject to the following two conditions:

1. This device may not cause interference.

2. This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

1. L'appareil ne doit pas produire de brouillage;

2. L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

DEFINITION OF SYMBOLS

	Caution	Per ISO 15223-1:2021
	Keep Dry	Per ISO 15223-1:2021
	Possible Hearing Damage	EN 50332-1:2013
	Manufacturer	Per ISO 15223-1:2021
	Distributor	Per 1522301-1:2021
	Serial Number	Per ISO15223-1:2021
	Lot Number	Per ISO 15223-1:2021
	Model Number	Per ISO 15223-1:2021
	Medical Device	Per ISO 15223-1:2021

	Consult Instructions For Use	Per ISO 15223-1:2021
	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 ISO 15223-1:2021
	Humidity Limitation	Per ISO 15223-1:2021
	Atmospheric Pressure Limitation	Per ISO15223-1:2021

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