

NightBalance Lunoa 1.0 FAQ's

Patient Device Questions/Answers

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| Q: I have a pacemaker/ICD (Implantable Cardioverter Defibrillator) can I use the Lunoa SPT? | A: The Lunoa device cannot be utilized by patients who have a pacemaker. Please refer to the instructions for use (IFU) for more detailed information regarding the operation of your device. |
| Q: I sleep in an upright position or propped up on more than two pillows. Can I use the SPT? | A: a. The Lunoa cannot be used by patients that sleep in the upright position or require more than two pillows during sleep. b. The Lunoa SPT is not recommended for the treatment of patients who are supposed to sleep in the supine position because of a medical condition (back/shoulder surgery or osteoarthritis). |
| Q: Do I need a prescription to get a Lunoa SPT? | A: Yes, the Lunoa SPT is indicated for prescription use for the treatment of adult patients with positional obstructive sleep apnea with a non-supine apnea-hypopnea index of <20. |
| Q: Can I get out of bed at night? | A: Yes, if you need to get out of bed during the night, you can pause the device. This will stop the device vibrations for a period of 5 minutes. To pause the device, you can either turn the strap with device vertical or just sit upright. |
| Q: Can I still sleep on my stomach? | A: Yes, the device functions in any sleeping position. |
| Q: What is in the package? | A: The packaging contains a user manual, torso strap, torso strap extension, charging base, charging cable, travel case and the Lunoa SPT device. |
| Q: How big is the Lunoa SPT device and its accessories? | A: a. Sensor device – 2.7 x 1.7 x 0.5 inches (6.9 x 4.3 x 1.2 cm). b. Docking station – 4.0 x 3.3 x 1.2 inches (10.2 x 8.3 x 3.0 cm). c. Chest strap – 41.3 x 2.4 x 0.1 inches (105.0 x 7.5 x 0.3 cm). |

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| | <p>d. Extension piece – 11.8 x 1.2 x 0.1 inches (42.0 x 3.0 x 0.3 cm).</p> <p>e. Travel case – 7.9 x 6.7 x 2.7 inches (20.0 x 17.0 x 6.8 cm).</p> |
| <p>Q: What is the warranty for the Lunoa SPT?</p> | <p>A: a. The Lunoa SPT device and docking station are warrantied for 2 years.</p> <p>b. The warranty will not cover:</p> <p>i. Any components that are subject to normal wear and tear. This includes the chest strap and sensor device batteries.</p> <p>ii. Any damage or malfunction due to incorrect use, unauthorized alterations or repairs to the device, or not storing the device as outlined in the Instructions for Use.</p> |
| <p>Q: How long can I expect to be able to use my Lunoa SPT device and accessories before I need to replace them?</p> | <p>A: Each accessory along with your device has an “In-Use life” this is the amount of time that each individual item can be used before needing to be replaced (this is sometimes referred to as the “service life”).</p> <p>a. Sensor device – 3 years</p> <p>b. Docking station – 3 years</p> <p>c. Chest strap – 1 year</p> <p>d. Extension strap – 1 year</p> <p>e. Travel case – 3 years</p> |
| <p>Q: Is there any maintenance that needs to be done to my device?</p> | <p>A: a. The sensor device and docking station do not contain any parts that can be serviced</p> <p>b. After the service life (equivalent to in-use life) of Lunoa SPT components has expired, replace the component with a new one.</p> |

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| <p>Q: How do I clean my device and accessories?</p> | <p>A: a. Wash the Chest Strap and Extension Piece on a regular basis (once per week or when visibly soiled) with a mild detergent not containing chlorine bleach or fabric softener. The Chest strap and extension can be washed in a washing machine (30 deg Celsius/86 deg F). After, let the straps air dry.</p> <ul style="list-style-type: none"> i. DO NOT place the sensor device in a wet Chest Strap ii. DO NOT dry the straps in a dryer iii. DO NOT iron the Chest Strap <p>b. It is the user’s responsibility to keep the Lunoa SPT device dust free.</p> <ul style="list-style-type: none"> i. To clean the Sensor Device and Docking Station, turn these devices off and wipe clean with a dampened cloth with water or mild cleaning solution (e.g. standard detergent) if they are visibly dirty ii. DO NOT use bleach or other aggressive cleaning solutions iii. Ensure that moisture does not penetrate the openings <p>Please refer to the instructions for use for more detailed information regarding the operation of your device.</p> |
| <p>Q: How do I know that I am placing the Sensor Device correctly?</p> | <p>A: a. Place the Sensor Device inside the Device pocket of the Chest Strap.</p> <ul style="list-style-type: none"> b. Check that the Device Pocket is placed in the middle of your chest. c. Make sure the Sensor Device’s buttons are on the top and the display is facing away from your body. |
| <p>Q: How do I know that the Lunoa SPT is turned on?</p> | <p>A: a. Power on the Sensor Device by sliding the ON/OFF switch to the ON position.</p> <ul style="list-style-type: none"> b. Confirm that the white LED light on the Sensor Device starts blinking. This indicates that it is switched on. |

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| <p>Q: How often should I charge my Lunoa SPT device?</p> | <p>A: a. Charge the Sensor Device at least once every other day for optimal performance.</p> <p>b. There is no harm in charging the Sensor Device every morning after use (recommended).</p> |
| <p>Q: Does my therapy begin as soon as I switch the device on?</p> | <p>A: No, the Lunoa SPT allows you 15 minutes to fall asleep once the device is switched on.</p> |
| <p>Q: Do I have to fall asleep on my side?</p> | <p>A: No. You may fall asleep in any position that you desire. Once the sensor vibrates turn to your side.</p> |
| <p>Q: Can I get a new or extra Chest Strap and Extension piece?</p> | <p>A: Yes, you can order an additional or replacement chest strap by contacting the FSSL or DME that you purchased the device from. PN# L1CHST01</p> |
| <p>Q: What is the adaptation program?</p> | <p>A: The Adaptation Program of the Lunoa is designed to gradually train your body to respond to the Sensor Device’s vibrations during sleep. The Adaptation Program is nine nights in total. You need to use the Lunoa for 9 nights before the device provides full positional therapy.</p> <p>a. Analysis Phase – no vibrations are given during the first two nights of the therapy. The Lunoa gathers baseline data on your sleep patterns during nights one and two. This data is used to tailor the therapy to your individual sleeping behavior later on.</p> <p>b. Buildup phase – the Lunoa starts to deliver vibrations. During nights three through nine of the therapy, the amount of vibrations when laying on you back build up gradually. This allows you to get used to the therapy.</p> <p>NOTE: It is recommended to use the Lunoa every night, or as agreed with your medical specialist for best therapy results.</p> |
| <p>Q: Will the USB ports allow a device to be plugged in and store data longer than 1 year?</p> | <p>A: The USB ports allow a USB pen-drive to be plugged in to store and transfer data (by manual upload) to the Portal. The Docking Station can store at least 1 year of data.</p> |
| <p>Q: Why are there 2 USB ports on the Docking Station?</p> | <p>A: The Lunoa SPT 1.0 provides 2 USB ports with identical functionality.</p> |

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| <p>Q: Does the device clear itself of data after data upload?</p> | <p>A: Data transferred to the Docking Station is (automatically) removed from the Sensor Device memory.</p> |
| <p>Q: Does the device retain data after the data has been transferred to the cloud (or USB memory stick)?</p> | <p>A: a. The Sensor Device will retain data up to the point it has been successfully transferred to the Docking Station. b. The Docking Station will retain data up to the point it has been successfully transferred to the Portal (via cellular connection). c. Transfer of data from the Docking Station to USB pen-drive will not cause the removal of data from the Docking Station.</p> |
| <p>Q: Is there a way to erase data from the device?</p> | <p>A: Connecting the Sensor Device to the Docking Station for charging and data transfer will erase data from the Sensor Device once it is successfully transferred to the Docking Station. If the Sensor Device is returned to NightBalance, the Sensor Device can be reset (erasing data). There is no other way for the patient to erase data.</p> |
| <p>Q: Will the sensor device always retain the last 7 days of data for the rolling 7 day average?</p> | <p>A: The Sensor Device can store (at least) one year of data. <i>Whenever the Sensor Device is full it will overwrite the oldest data first, and thus since 7 days is less than 365 days the data is retained.</i></p> |
| <p>Q: Can I factory reset the device?</p> | <p>A: No, The Sensor Device can only be reset under a qualified process. Currently this is done at the production site and is not available per patient request.</p> |
| <p>Q: Can this be used for multi-patient use?</p> | <p>A: No. The product is intended for single-patient use.</p> |
| <p>Q: Is there a certain brand of USB stick that should be used or was tested with the Lunoa 1.0?</p> | <p>A: Any USB stick that supports USB 2.0 will work. Some USB sticks may not fit due to recessed USB port on the docking station.</p> |
| <p>Q: Is there a certain memory size needed for the flash drive?</p> | <p>A: The smallest commercially available USB pen-drive of 64 MB is already sufficient for 1 year of data.</p> |
| <p>Q: If the device has a Time Reference Error, does it need to have a cellular connection to update the Sensor Devices time and date?</p> | <p>A: No, the device has an internal clock chip to reset the date/time.</p> |
| <p>Q: Can I use the Lunoa device with Home Sleep Test (HST) devices?</p> | <p>A: No, use in combination with HST devices is not mentioned as the intended use of the product (see</p> |

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| | IFU). If a patient wishes to use the Lunoa SPT device with another medical device or therapy, they should consult their medical specialist. |
| Q: Would there be any sort of interference with CPAP/BiPAP units using Bluetooth to communicate? | A: The product complies with the standards applicable for the intended use. If a patient wishes to use the Lunoa SPT device with another medical device or therapy, they should consult their medical specialist. |
| Q: If a replacement device is sent out will the new device pick up where the old one left off, treatment-wise, or will it need to reanalyze and start over? | A: Replacement device will start over. Data from old device to new device cannot be merged. |
| Q: Is there a charge for cellular upload? If so, how is billing handled? | A: No, the cellular connection fee is not to be paid by the end-user. It is built into the cost of the eSIM component. |
| Q: Who is the provider of cell service to allow the chip to upload? | A: The networks used in the US are provided by T-Mobile and AT&T. |
| Q: What type of memory is in the device? Flash? | A: The Sensor Device has Flash Memory. |
| Q: Is there a capacitor that stores energy when the battery is fully discharged for memory purposes? | A: The Sensor Device does not lose the recorded sleep data when the battery is fully discharged (non-volatile memory). |
| Q: How many battery charging cycles are available with this device? | A: > 1000 cycles. |
| Q: What is the average amount of data collected per night (file size)? | A: 8-50 kB per day depending on the user (duration, number of vibrations, events...). |
| Q: Can the data acquired be exported to CSV? | A: No. |
| Q: Does the time on the device sync with the cellular signal? If not, how does the time sync especially if people aren't using the cell chip due to poor coverage? | A: Yes, the Docking Station will sync the time via cellular connection and the Docking Station has a back-up battery for the clock. (real-time clock). |
| Q: How many options for strength and pattern of vibration are available, since the device tailors itself to each patient? | A: There are 10 Levels of Vibration and 5 Vibration Patterns. These are inbuilt into the device and cannot be changed by the patient. |
| Q: Is there an FAA letter for this device to carry on an airplane? | A: No, not at this time. |
| Q: If a patient were to bring this in a sleep lab, will this interfere sleep | A: The product complies with the standards applicable for the intended use. If a patient wishes to use the |

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| recording system and or study while patient is wearing this? | Lunoa SPT device with another medical device or therapy, they should consult their medical specialist. |
| Q: Can a patient use the USB ports to charge their cell phone? | A: No, this is not recommended and should not be promoted. |
| Q: If a patient has the dock and forget their power supply, can they plug in their charged cell phone to charge the Lunoa? | A: No, the USB ports do not provide power output. |
| Q: How long does the device need to be in the up position to put it into the pause mode? | A: +/- 5 seconds. |
| Q: How long will a fully charged battery last? | A: Per the Instructions for Use, the battery must be charged at least every other day. |
| Q: If a device comes in for replacement, can service pull the existing data off of the device and add it to the patients portal account for compliance reasons? (this would be important when we get insurance reimbursement). | A: No. |

Patient Portal Questions/Answers

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| Q: Can a profile have the email changed to a new/different address? | A: Yes in the patient portal menu. |
| Q: If I chose the wrong Physician at first then I switch to the correct Physician, will the first Physician (incorrect chosen) be able to see the patient data? | A: Up to the point where you switch the Physician; Yes. After the point where you switch the Physician; No. |
| Q: How fast does the data upload from the sensor device (while in dock) to the portal? How long does it take to get the data to the portal? | A: Depends on the number of days of data that have not been uploaded. For 1 day of data; a couple of seconds. |
| Q: How do we handle cloud maintenance scheduling/outages? | A: The Docking Station will retry upload at later time after the maintenance period is complete. |

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| <p>Q: If I do not make the 15-minute window for activation, can I use the same user name and password be used to start the registration process over?</p> | <p>A: Yes.</p> |
| <p>Q: My therapy data is not visible in the Lunoa Portal.</p> | <p>A: There are a few possible causes why the therapy data may not be visible in the portal:</p> <ul style="list-style-type: none"> a. Therapy data is only visible in the Portal if you have activated your account. If you have not yet set up an account, please do so via the registration option of the Portal at http://us.mylunoa.com b. The Docking Station must be powered, and the Sensor Device should be placed on the Docking Station to upload therapy data. Refer to the “Getting Started” section in the Instructions for Use. c. The Portal shows your therapy data from the buildup phase and onward. During the first 2 days of use, the Sensor Device is collecting baseline information. d. Therapy data needs several minutes to be uploaded and processed by the Portal. |
| <p>Q: Where is the portal hosted and does it meet international guidelines for international travel outside the US?</p> | <p>A: Portal Hosted in the US for US patients and Germany for EU patients.</p> |
| <p>Q: If a patient gets a replacement device will the physician that they have chosen see both old and new data?</p> | <p>A: Yes.</p> |
| <p>Q: I am going to be away and will not be able to download my device. What should I do?</p> | <p>A: If you are unable to connect while you are travelling, note that the docking station will not upload new sleep data to the Portal. The docking station can store up to one year of sleep data in its memory, so you can wait for you return to connect to the portal and upload your data.</p> |

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| Q: Where can I find the serial number that I need for registration in the Lunoa Portal? | A: The serial number is located on the back of the Sensor Device. |
| Q: How does the Docking Station transfer data to the Lunoa Portal? | A: The Lunoa automatically sends the data from the Docking Station to the portal via a cellular connection when it is cradled in the Docking Station. |
| Q: How can I upload my data to the Lunoa Portal without cellular coverage? | A: If you do not have cellular coverage, you can use a USB stick to upload your data from the Docking Station to the Portal. The Instructions for Use provides a guide to upload your data to the Portal in the “Troubleshooting” section. |