happiest baby

FAQs for Hospital Mobile App Use

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More questions?

Please give our Customer Care team a call at **855.424.6323** or email us at <u>customercare@happiestbaby.com</u>. We are here to help!

1. Is it required to use the SNOO's mobile app in the hospital?

It is **not required** to use the SNOO's mobile app. Many hospitals do not use it, but some do.

The benefit of the mobile app is that it has features that clinical care teams may find helpful (e.g., Motion Limiter, Level Lock, Weaning Mode, Sleep Logs...all described in the SNOO's "User Guide"). However, **the SNOO is still perfectly functional without ever connecting to the app.**

To turn on SNOO manually, simply place the swaddled baby into the bassinet, secure the wings of the SNOO Sleep Sack over the safety clips, and push the lighted Activity button. SNOO will begin gentle rocking and white noise. It will automatically respond to infant crying with four additional levels of specially designed sound and motion, which imitate the actions experienced caregivers use to soothe fussing and return babies to sleep.

In clinical settings, we recommend that caregivers remove the baby from the bed if the infant is not clearly calming after 1-1.5 minutes at the higher levels (usually indicating the need for a feeding, diaper change, or snuggle). If the baby is not calmed by SNOO within 3 minutes at the highest level, SNOO automatically stops.

Caregivers can also manually raise the level of the SNOO by holding the Activity button for a few seconds. The button will change color and SNOO will quickly go up to the next level.

To stop SNOO, just push the Activity button once or slip a loop of the swaddle wing off the safety clip.

2. If the Motion Limiter feature has not been enabled, are the motion and sound levels safe for preemies and other fragile infants in the NICU?

Every baby in the NICU and nursery is unique, and their individual needs and vulnerabilities need to be considered before using any intervention.

SNOO's motion and sound are safe for normal infants and premature babies (4 lbs. min. weight). It can be used to approximately six months of age (25 lbs. max and/or able to get up on hands and knees).

However, we **do not** recommend using SNOO for infants whose condition may be worsened by the bed's back and forth motion. For example, we would suggest restricting use for babies with neurological or spinal defects, bleeding tendency (hemophilia, anticoagulant therapy, intracranial bleeding, etc.), hydrocephalus, or post-neurological surgery.

SNOO's platform is designed so that it cannot move more than one inch back and forth during the low levels and at the higher levels the motion is capped at 0.25 inches (0.5 centimeters), which is similar to what a baby might experience being driven on a bumpy road.

SNOO's white noise sounds are specifically engineered to soothe infants by mimicking womblike sensations. The sound on the blue level is ~68dB (measured at the baby's ear), and its highest volume at the pink level is ~85 dB, which is significantly less loud than a newborn's own cries, which measure 100-110dB.

There is minimal evidence that extreme quiet (sound levels below 50dB) is physiologic for premature infants or full-term babies. In fact, it may be considered a subtle form of sensory deprivation. Intrauterine sound levels have been measured at 72-95 dB.¹ Additionally, **sound has been shown to reduce infant crying from painful nursery procedures.**² A small study evaluating the sound used by SNOO demonstrated a reduction in hypoxemic and bradycardic events in preterm infants.³

It's absolutely true that there's still a lot to learn about the impact of noise environments on neonates, but rest assured knowing that the shushing white noise of the SNOO is designed with scientific principles in mind, and that our sounds are distinct from high-pitched alarms and alerts that many hospitals are seeking to minimize.

3. Does the SNOO collect PHI? Is the mobile app HIPAA-compliant?

By default, SNOO does not collect protected health information (PHI), confidential business data, or payment card industry data (PCI), and is therefore not subject to the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

If you sync your SNOO the mobile app (must be done over WiFi), you can track infant sleep and fussiness over time. SNOO is an "Internet of Things" (IoT) product that, when enabled, can collect timestamps for when SNOO is turned on/off and when it changes levels. Based on these inputs, the mobile app generates a Daily Log illustrating total sleep duration, longest period of sleep, and frequency of waking. However, SNOO does not require collection of any personally identifiable health information and is therefore not subject to HIPAA when used as directed.

Data collection is an optional feature that may be disabled in the app. During setup, a **Data Preferences** page will appear, on which you can accept or decline various tracking and reporting options. To change the data collection defaults after the account has already been set up, go to **Help and Feedback** (the little question mark on the lower right-hand side of the app) and select **Manage Data Collection** to toggle on or off preferences.

If you have any trouble navigating through the Daily Log page, please call our Customer Care team at 855.424.6323. They are available to support you and answer questions 7 days/week!

4. What security features are present for SNOOs linked to the mobile app?

¹ Smith CV, et al. 1990; Walker D, et al 1971.

² Harrington, 2012; Setiyorini & Wulandari 2014; Martiningsih & Setijaningsih 2015.

³ Parga, et al. 2017.

Happiest Baby has a very robust and independently tested privacy and security infrastructure. And, it is continuously fortifying SNOO's software safeguards against any type of intrusion. SNOO also has built-in hardware limiters. The sounds cannot exceed the level of a baby's cry and the platform cannot be made to move more than 1" to either side.

Once the mobile app is set up, the account linking the SNOO to the account is password protected and cannot be reassigned to a new email address without manual reprovisioning from the HBI team. To transfer ownership of the mobile app account, you would need to contact our Customer Care team at 855.424.6323 or <u>hospitals@happiestbaby.com</u> and provide verification from the primary hospital contact or research study's Principal Investigator, along with an image of the barcode located on the bottom of the SNOO.

5. Can the Wi-Fi feature be manually disabled?

Yes. SNOO was designed to give babies all SNOO's sleep and safety benefits without needing to connect to a wireless network. Users are also given the option to completely disable SNOO's Wi-Fi connectivity, simply by clicking off the Wi-Fi button.

This button is underneath the SNOO (on the same end of the bed as the Activity Button). The Wi-Fi button is the smaller of the 2 buttons (it has a WI-Fi symbol printed on it). To turn it off, simply press on it so that it **pops out**.



6. Does the mobile app require a dedicated tablet or smartphone?

No, the mobile app does not require a single smart device to be linked to the SNOO. Any smartphone or tablet with access to Apple® App Store is supported. However, the account credentials will be required for login once the SNOO has been linked to the mobile app.

Many hospitals choose to dedicate a tablet or smart device to the SNOOs so that various members of the clinical care team can toggle the levels and settings as desired.

For any questions about using the SNOO App on your mobile device, please contact our Customer Care team at customercare@happiestbaby.com, or call 855.424.6323.

7. Can I link multiple SNOOs to the same mobile app account?

Yes. The *Switch Account* feature allows you to connect multiple SNOOs to a single mobile app account, instead of having to log in and out to control different units. To set up the feature, make sure you have the newest version of the iOS SNOO App and head to the *Settings* page.

If you already have each of your SNOOs paired to a device, you can reset by going to **Accounts,** <u>then</u> **+Add Account** and logging into the SNOO account that you want to link. If you have just received your SNOOs, you must first pair them individually, by selecting **Sign Up** and creating an account. Repeat this step for as many SNOOs as you have.

Then, to hop from one SNOO to the next, simply click on the SNOO you would like to view and control. To modify any settings, simply click on the **Settings** page to modify features to fit that specific baby's preferences.

8. Can I create multiple profiles for different babies in the same SNOO?

To discourage clinical care team members from inadvertently inputting protected health information into the mobile app profiles, multiple clinicians cannot create profiles for the same SNOO.

9. Is the SNOO mobile app compatible with Enterprise wireless networks?

No. The SNOO mobile app is not compatible with open or Enterprise networks. As a workaround, hospitals may elect to rent or purchase Wi-Fi hotspots to enable the app.

In select cases, a hospital conducting an IRB-approved academic research study may be eligible for a free Wi-Fi hotspot or monthly stipend through Happiest Baby, Inc. to cover the cost. Please contact <u>hospitals@happiestbaby.com</u> for information.

10. What steps do I need to take to set up the SNOO mobile app at my hospital?

The steps to set up the SNOO mobile app may vary, depending on the IT processes and protocols at your hospital. The hospital may require the review and approval of its IT department to ensure the device meets the institution's safety and privacy standards. Please contact your hospital's Director of Informatics or Information Security team to learn more.

If your hospital requires vendor approval for connectivity, please send required forms and requests to <u>hospitals@happiestbaby.com</u>.

11. My hospital's policies restrict the use of all external mobile apps. Would there still be any way to enable the various mobile app features manually?

For hospitals using SNOOs with preemies or other fragile infant populations who would benefit from the **Motion Limiter** setting, Happiest Baby, Inc. may be able to provide custom SNOOs that have Motion Limiter as the default setting.

Please contact <u>hospitals@happiestbaby.com</u> to learn more.