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Nox T3s®, Nox A1s®, Nox C1 and Noxturnal® are manufactured by:

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# nox medical

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#### **Overview**

This Release Bulletin announces the release of the following Noxturnal softwares and CD's

- Noxturnal 7.1.0 38712
- Noxturnal US 7.1.0 38712
- Noxturnal Language Pack 7.1.0 38712

The software also contains new versions of the Nox T3s and Nox A1s firmware:

- Nox T3s Firmware 3.1.0.2780
- Nox A1s Firmware 3.1.0.2780
- Nox C1 Firmware 1.4.0.324

The main aim of this release is to introduce Noxturnal 7.1 which introduces several new features and improvements to the field:

- Adds support for 10-20 referential and bipolar EEG montages through integration of the Lifelines R40 EEG amplifier.
- Enhancements to the Nox SAS including an updated Frontal Filter for SAS EEG signals
- Improvements to 4% AHI reporting
- Important bug fixes derived from user feedback

Firmware upgrades that add new features and improvements to the Nox A1s, T3s and C1 devices

- Starting recording by attaching the RIP belt
- Successful Study Indicator feature
- Ability to wake Nox A1s via Bluetooth
- Improved Bluetooth connection between Nox A1s and C1

Finally, this software release also contains an updated version of the Noxturnal Language Pack and product manuals (T3s, A1s and Noxturnal manuals), supporting the following languages:

- Chinese
- Czech
- Danish
- Dutch
- Finnish
- French
- German
- Italian
- Japanese (no updates for JP manuals in this version)
- Norwegian
- Polish
- Portuguese
- Spanish
- Swedish

# **Downloading Software**

The software can be downloaded from different download locations and is available on the Nox Support Site.

Noxturnal, Noxturnal US & Noxturnal Language Pack

www.noxmedical.com/download

Noxturnal - Using Dropbox

Noxturnal US – Using Dropbox

Noxturnal Language Pack – Using Dropbox

Nox T3s Firmware - Using Dropbox

Nox A1s Firmware - Using Dropbox

# **List of Features and Bug Fixes**

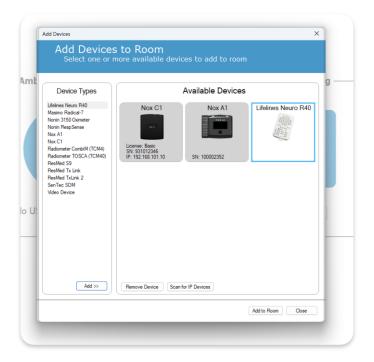
The following features and bug fixes are included as a part of the **Noxturnal software** with this release:

# Features new to Noxturnal 7.1:

Some of these features are hardware specific and require firmware updates. Please see the compatibility section for minimum requirements.

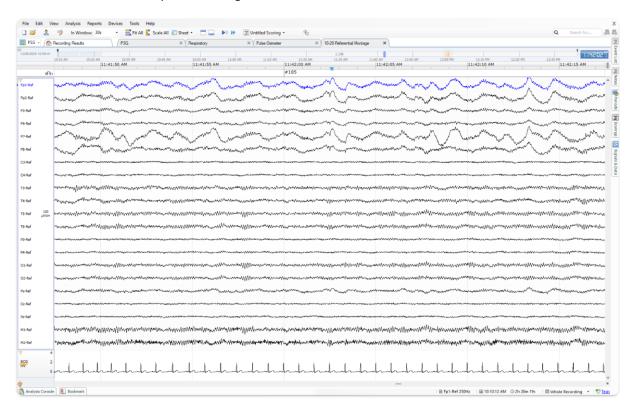
## Integration of the Lifelines Neuro's R40 EEG Amplifier to the supported Device Types.

- The <u>Nox Medical Support site</u> will have more detailed information on the set-up and use of the Lifelines Neuro's R40 EEG Amplifier with the Nox PSG System.
- Direct digital connection to the Nox PSG system via USB connection to the Nox C1 Access
   Point



- The Lifelines Neuro's R40 EEG Amplifier allows for the recording of 26 unipolar channels and 2 additional bipolar. Channels supported at launch:
  - o 21 EEG inputs
  - o 2 EOG inputs
  - o 3 chin EMG inputs
  - 2 additional bipolar channels (4 bipolar inputs also available on the Nox A1s recorder)
  - REF and PGND

- Signals from the Lifelines Neuro's R40 EEG Amplifier are sampled at 16kHz and stored at 250
   Hz for viewing in Noxturnal
- Impedance check from Lifelines Neuro R40 amplifier in Noxturnal
- Lifelines Neuro's R40 EEG Amplifier records EEG and EOG signals in referential mode allowing for the creation and viewing of multiple montages:
  - 10-20 Referential EEG Montage
  - 10-20 Bipolar Montage



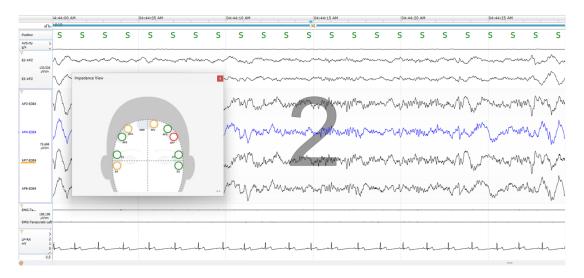
- Lifelines Neuro's R40 EEG Amplifier studies have the ECG artifact filter disabled as it not supported
- Lifelines Neuro's R40 EEG Amplifier requires a Nox C1 Access Point, Nox A1s, and Nonin Oximeter 3150 BLE to perform PSG studies.
  - The Lifelines Neuro's R40 EEG Amplifier integration records EEG, EOG, chin EMG, and offers for the addition of two extra bipolar channels
  - The A1s records the other signals required for a PSG (ECG, Nasal Flow, RIP, limb EMG etc.) When a R40 study is configured, the Nox A1s has the unipolar inputs turned off (EEG, EOG, and chin EMG inputs on the A1s)
  - o The Nonin Oximeter 3150 BLE records SpO2, heart rate etc.

## Improvements to 4% AHI reporting workflow

- Add 4% AHI REM and NREM parameters
- Added a color-coded 4% AHI Report Part
- Added Pre-PAP 4% report parameters to improve split-study workflows
- Added 4% Report Parts for easier report template creation

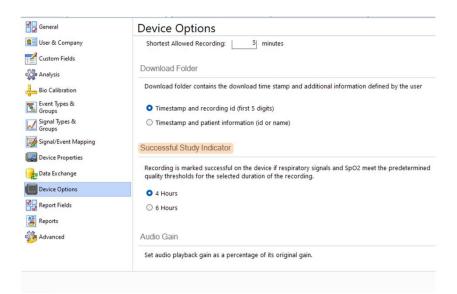
## **Improved Nox SAS support**

- Noxturnal 7.1 features an updated SAS Frontal Filter which makes the EEG signals recorded with the SAS Head Cable more closely resemble PSG EEG signals.
- Added SAS impedance sheet to the list of standard sheets
- Added Impedance View for the Nox SAS head cable



# **Successful Study Indicator**

- When ambulatory/HST recording is done, the patient can check if the recording was successful and has the option to redo the recording without sending the device back.
- Option added under Settings to adjust the duration required for a successful study to 4 or 6
  hours. This is the minimum duration the defined signals must meet the quality threshold for
  the study to be considered successful.

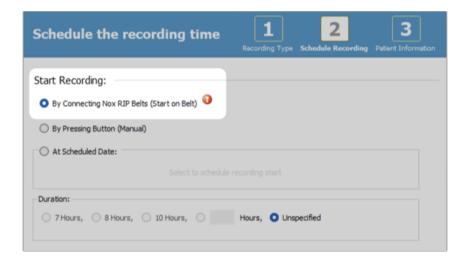


- Study quality is evaluated on the device (Nox A1s and T3s) when the recording finishes and the result is displayed on a menu on the device.
- If one of the scheduled recordings fails, one extra scheduled recording is automatically added with the same start configuration as the initial study.
- For A1s and T3s studies, the minimum required signals of SpO2, and two out of the three respiratory signals of thorax and abdomen RIP belts, and Nasal Cannula will need to be recorded for the successful study indicator to correctly function.
- Following the sleep study, the patient presses the button on the A1s or T3s device three times to go to the successful study indicator menu. The third screen displays the Study Quality Status for each night:
  - 1. Checkmark for a successful study
  - 2. X for a failed study
  - 3. Empty checkbox for a study that is not done or automatically rescheduled following a failed study (if scheduled start time is set in Noxturnal)



#### **Start Study with RIP Belt attachment**

 This new feature adds a third option to the study configuration settings to schedule a recording to start when the clinician or the patient attaches both ends of the Thorax RIP belt to the device



- Use Noxturnal 7.1 to Schedule the recording time to start when the RIP belt are attached to the device
- Insert battery into the Nox A1s or T3s device. There is no need for the clinician or patient to press the button as the device enters a low power mode until the RIP belts are attached
- The study starts when the clinician or patient attaches both ends of the Nox Thorax RIP belt to the device
- The study stops if Nox Thorax RIP belt is disconnected for >30 seconds OR the battery runs out



#### Wake on Bluetooth for Nox A1s and T3s.

 The new low power mode for the Nox A1s and T3s recorders enables the start on RIP feature and enhances PSG lab workflows by allowing the A1s to turn on and start a recording from Noxturnal

- Once the battery is inserted into the device, it enters a low power mode, and can be woken to start a recording from Noxturnal
- For Online Studies, this means no more having to go into the room to turn on the device to start a study

## **Bug Fixes:**

- REM Latency Calculation: In previous versions, the REM latency parameter was calculated from the analysis start instead of sleep onset
- Custom Fields Default Value Bug: A bug with custom fields' default values was introduced in Noxturnal 7.0.
- AHI 4% Supine Parameter Error: In Noxturnal 7.0, the AHI 4% supine parameters incorrectly used Total Sleep Time (TST) instead of TST supine for the denominator
- PAP Table Format Issue: A format issue with the PAP table was introduced in Noxturnal 7.0.
- Arousal Tool Failure: An issue in Noxturnal 7.0 caused the arousal tool to occasionally fail

# Nox Medical Recorder Firmware Update (T3s and A1s)

#### Nox A1s Firmware, version 3.1.0

Add the following new features outlined above (see requirements table below):

- On device successful study indicator
- Wake on Bluetooth with new low power mode following insertion of battery into device
- Start and end recording with RIP belt attachment or removal for ambulatory studies

#### Nox T3s Firmware, version 3.1.0

- On device successful study indicator (post-study indicator)
- Wake on Bluetooth with new low power mode following insertion of battery into device
- Start and end recording with RIP belt attachment or removal for ambulatory studies

Feature	A1s firmware	T3s firmware	C1 Firmware	Noxturnal Version
Successful Study Indicator	3.1.0	3.1.0	N/A	Noxturnal ≥7.1 to adjust duration in settings
Wake on Bluetooth	3.1.0	3.1.0	N/A	Noxturnal ≥7.1
Start on RIP Belt attachment	3.1.0	3.1.0	N/A	Noxturnal ≥7.1
Lifelines R40 Amplifier Support	3.1.0 recommended	N/A	1.4.0	Noxturnal ≥7.1
Improvements to A1s and C1 connection	3.1.0	N/A	1.4.0	Noxturnal ≥7.1

# **Upgrade Recommendation and workarounds for Nox Users**

# **Noxturnal Upgrade Wizard**

#### Noxturnal 7.1.0

Noxturnal 7.1.0 has a built-in upgrade wizard for all users upgrading from 5.X or 6.0 versions of Noxturnal. This upgrade wizard prompts the user with selections on if they want to upgrade with old settings as a part of the install procedure or if they want a fresh install.

#### Noxturnal US 7.1.0

## **Upgrading from Noxturnal US 6.x.x**

The Upgrade wizard will pop up with information if the user wants to maintain old user settings or if they want to do a fresh install.

## Upgrading from version 5.x or older

If upgrading in the US market from a version 5.x or older consider these upgrade instructions <u>here.</u>

## **Older Noxturnal Versions**

If users are working on an older version of Noxturnal (3.X and 4.X) it is recommended to do a fresh install and setup of the software since so many things have changed in recent releases and updating on top will create more problems than it solves.