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006921

Nitelog

Instructions for Use: English

For use with Z1 Auto & Z2 Auto CPAPs
on compatible Android mobile device

Ref: 006003

version 2.2



Contents



Please read all the instructions in this Help Guide before using Nitelog.

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About this Manual

This Nitelog User Manual provides information on how to use the proprietary mobile app, Nitelog, to enhance the use of the Z1 Auto or Z2 Auto. Nitelog's functionality ranges from device remote control to data viewing via its embedded Bluetooth capability. Please note all Z1 and Z2 functions can be controlled without the use of this mobile app directly through the device. Nitelog is compatible with both Z1 Auto and Z2 Auto CPAP systems from Breas Medical.

This Nitelog User Manual is meant to supplement the information in the Z1 Auto User Guide or Z2 Auto User Guide that was provided with the purchase of the Z1 Auto CPAP or Z2 Auto CPAP. It is not intended to replace the User Guide. As such, the owner/user of the Z1 or Z2 Auto System is responsible for reading and understanding the User Guide. The user is responsible for any injury or damage that results from:

- Operation of the Z1 or Z2 other than in accordance with the operating instructions contained in the User Guide supplied.
- Unauthorized maintenance or modifications to the device or attached accessories.

Medical Information:

Indications for Use:

- Your Z1 or Z2 Auto System is a single patient, reusable device that provides continuous positive airway pressure (CPAP) to support treatment of adults weighing over 66 lbs (30 kg) with obstructive sleep apnea (OSA).
- Please see the Z1 or Z2 Auto User Guides for Contraindications and Adverse Effects that may occur during the use of this medical device.



Warnings:

- U.S. Federal law restricts this device to sale by or on the order of a physician. **Rx Only**
- Use your Z1 or Z2 and its accessories only for their intended use as described in the User Guide supplied with the Z1 or Z2 Auto CPAP and as directed by your physician, clinician or healthcare provider.

Data













All sleep data generated through Nitelog is stored directly on the iOS device until you manually log out of the app and if you choose, our secure data cloud. If you logout of the app the data is deleted from the iOS device and will need to be resynced either from the cloud or the Z1 or Z2 Auto CPAP. The cloud service is free of charge and backs up all of your sleep data. You can use the cloud to backup your data and restore it to another iOS device. The option is located in the app under Data in the menu.

The data is stored anonymously and is only accessible from within the Nitelog app with your proper credentials.

Symbols & Icons

Icons in this Manual:

In this manual, icons are used to highlight specific information. The meaning of each icon is explained in the table below:

Symbol	Meaning	Description
	Warning	Highlight potential mis-use of the application or data contained within EveryWare
	Caution	Risk of equipment damage, loss of data, extra work, or unexpected results
	Note	Information that may be valuable but is not of critical importance, tips
	Reference	Reference to other manuals with additional information on a specific topic
	Follow Instructions for Use	Refer to this Instructions for Use/Help Guide
	Consult Instructions for Use	The User must consult this Instructions for Use / Help Guide
	Manufacturer	
	Serial Number	
	Product Number	
	Date of Manufacture	
Rx Only		U.S. Federal law restricts this device to sale by or on the order of a physician
	CE	Meets all requirements for CE marking according to applicable European health, safety and environmental protection legislation
	Medical Device	This product is a medical device

Manufacturer Information

Legal Manufacturer:



Breas Medical AB

Postal Address: Breas Medical AB, Företagsvägen 1, SE-435 33 Mölnlycke Sweden.

Email Address: breas@breas.com

Phone: +46 (0) 31 868800

Fax: +46 (0) 31 868810

U.K Responsible Person:

Breas Medical Ltd.

Postal Address: Breas Medical Ltd., Unit A2, The Bridge Business Centre, Timothy's Bridge Road, Stratford upon Avon, CV37 9HW, U.K.

Email Address: orders@nippyventilator.com

Phone: +44 (0)1789 293460

Fax: +44 (0) 1789 262470

Adverse Effects:

If a serious incident has occurred in relation to the Z1/Z2, please report it to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.



Customer Support & Privacy Contacts

Nitelog Customer Support - North America: EveryWareTechnicalSupport@breas.com

Address: Breas Medical - US Headquarters , 16 Esquire Road, Suite A, North Billerica, MA 01862, USA.
Tel: +1 (855) 436 8724

Nitelog Customer Support - United Kingdom & U.K Responsible Person: EveryWare.Support@Breas.com

Address: Breas Medical Ltd. Unit A2, The Bridge Business Centre, Timothy's Bridge Road, Stratford upon Avon, CV37 9HW, U.K.
Tel: +44 (0)1789 293 460

Nitelog Customer Support & Manufacturer - Global: EveryWare.Support@Breas.com

Address: Breas Medical AB, Företagsvägen 1, 435 33 Mölnlycke, Sweden.
Tel: +46 (0)31 86 88 00

Privacy: Privacy@Breas.com

Breas is strongly committed to protecting the privacy of your personal information. The Privacy Notice & Statement and the Terms of Conditions can be found by clicking on the Help icon on the left-hand side menu bar.

Breas Medical Information Governance Officer and data protection representatives can be contacted directly here:

Address: Breas Medical AB, Företagsvägen 1, 435 33 Mölnlycke, Sweden.
Tel: +46 (0)31 86 88 00

Requesting a Copy of this e-Instruction for Use / Help Guide:

- An authorized User of Nitelog can request a printed copy to be made available to them within 7 calendar days free of charge, by contacting the Customer Support contact above.



Security Guidance Recommendations


Breas uses a combination of technical and administrative security controls to maintain the security of your data. For example, we use strong encryption when you allow the transmission of data from the Nitelog App to our Device data cloud and when your data is at rest either on the Nitelog App or in our Device data cloud (if you choose to store your data there). Despite the security measures employed by Breas, you should be aware that it is impossible to guarantee absolute security with respect to data protection. If we confirm that your personal data has been subjected to a data breach, we will follow applicable data breach notifications laws.

If you choose to store your Device data in the Nitelog App on your smart device, we recommend that you:

- Enable the remote data wipe function on your smart device as this allows you to remotely erase personal data from your smart device if it goes missing (refer to your smart device user instructions)
- enable PIN or fingerprint security on your smart device (refer to your smart device user instructions)
- avoid unsafe modification of the smart device operating system such as “rooting” or “jailbreaking”
- keep your operating system up-to-date with security patches
- update your Nitelog App whenever updates are available from the App Store™ and Google Play™ store. Ensure that you always have the latest version installed on your smart device.

We will make reasonable efforts to ensure that the personal data collected is the minimum necessary to fulfil the purposes described in this Privacy Notice.

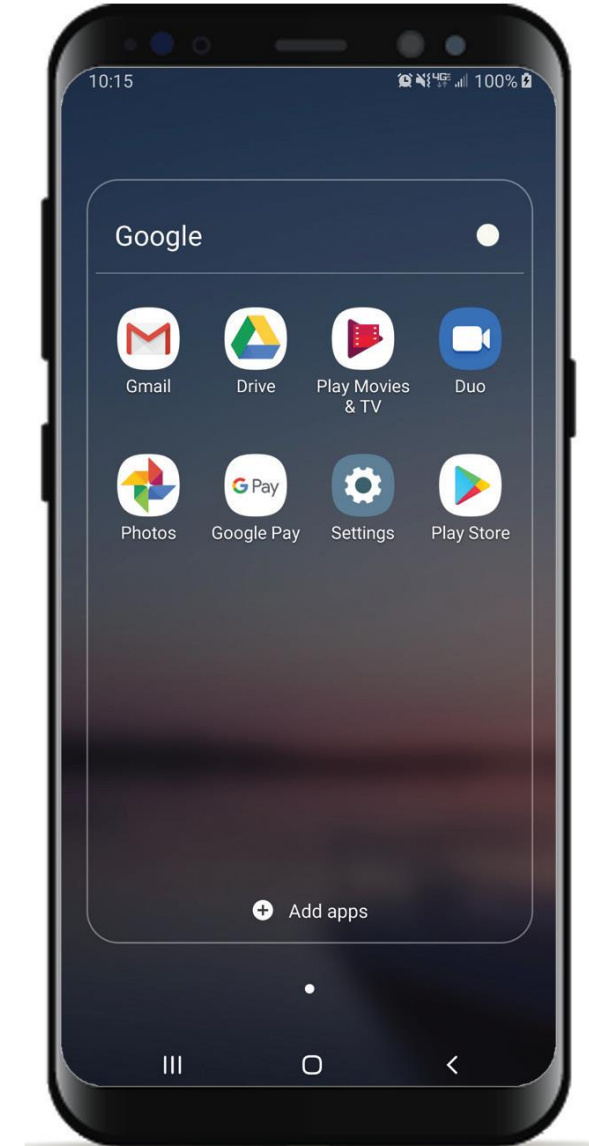
Getting Started

- Download the Nitelog App from the App Store to your iOS phone or tablet.
- On the Home screen of your phone or tablet, press the Play Store icon.
- Press the Search bar and search for “Nitelog”. 
- Press the GET button. Then press the OPEN button to download it to your phone or tablet. If you already have an older version of the App installed, you will need to delete the old version. The new version will not update the old one.




TURN ON BLUETOOTH

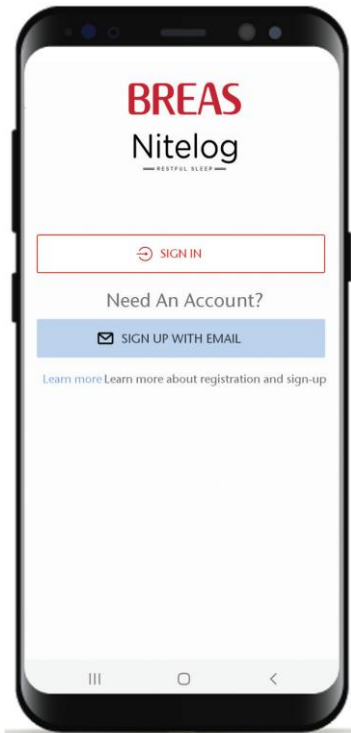
- On your Z1 or Z2, confirm that Bluetooth is turned on. Unplug your Z1/Z2.
- Press and hold the UP Arrow button while you insert the Power Cord into the CPAP until you see bt-On appear on the display. To turn off the Bluetooth, press and hold the DOWN arrow while inserting the PowerCord.
- Confirm that the Bluetooth is turned on for your Android mobile device.





Sign In Screen

- Plug in the Z1 or Z2 using the power cord or PowerShell®.
- Start the Nitelog App by pressing the Nitelog App button on your Android phone or tablet. 
- When the Nitelog App launches, you will see the title screen. After that the Sign In page appears.



The first time at the Sign In page, press the blue button “SIGN-UP with EMAIL”.



Create an account by typing in your personal information and create a password.

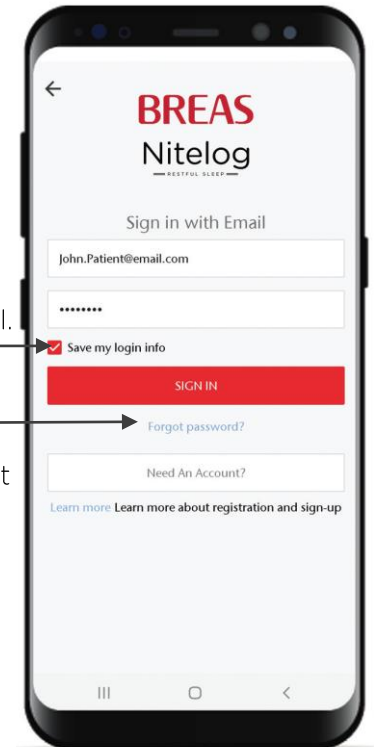
The first four lines of information will appear on the Compliance Report.

Press red button “SIGN-UP” to complete the process.

Nitelog will send a 6 digit confirmation code to your email address. Enter this code to complete the account set up.

Select “Save my login info” to save Password and email.

Select “Forgot Password” to reset your password.



After the first time, you will press the “SIGN IN” button and sign in using your email address and password.

Dashboard and Menu Items

- Plug in the Z1 or Z2 using the power cord or PowerShell®.
- Start the Nitelog App by pressing the Nitelog App button on your phone or tablet.
- When the Nitelog App launches, you will see the title screen. After that the Sign In page appears.

Dashboard

The first screen is the Dashboard.

The three lines in the upper left hand corner of any screen opens the Menu. Press the three lines to go to the Menu.

Menu Items

“Dashboard” returns to Dashboard.

“Current Device” shows the LCD screen of the connected Z1/Z2 or takes you to the connect to a device option.

“Data” syncs the sleep data.

“Goals” sets and views sleep goals.

“Profile” displays your personal information.

“Compliance Report” generates a Compliance Report.

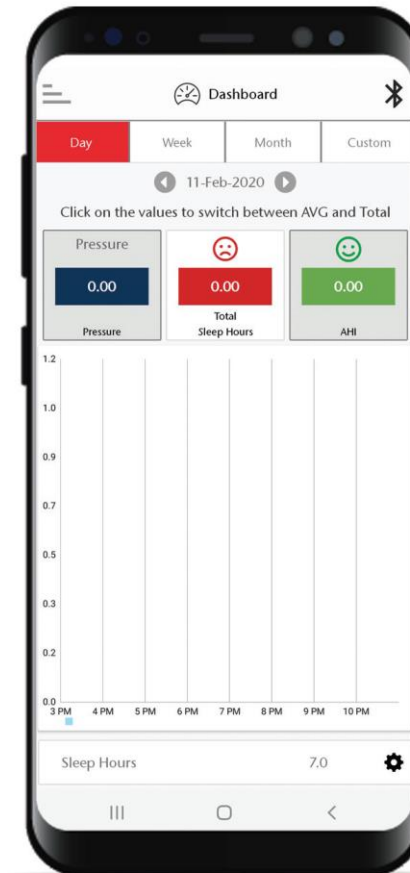
“Help” links to the Nitelog User Guide.

“About” shows information about the Nitelog App.

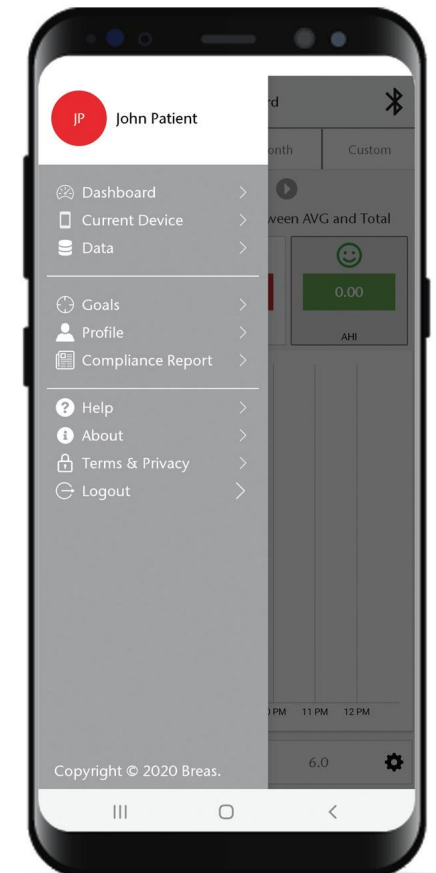
“Terms & Privacy” shows the Terms & Conditions of Use and Privacy Statement.

“Logout” Logs you out of Nitelog.

Dashboard



Menu

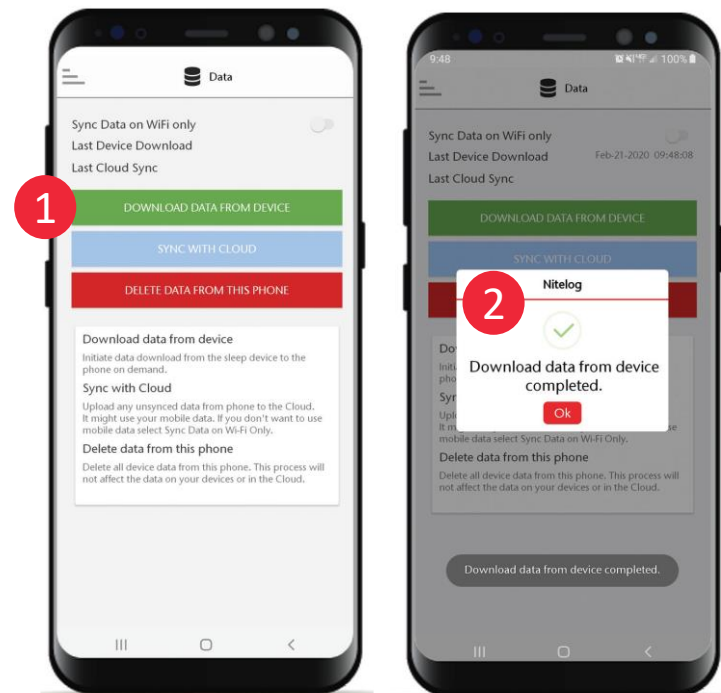


Data Screen



Sync Data with Nitelog

Press the Menu icon and select “Data”, to sync the sleep data on your Z1 or Z2 with the Nitelog App.

- Press the green “Download Data from Device” button.
 - You will need to do this every time you want to see new sleep data. If the mobile device is not connected to the Z1/Z2, you will see “No Device Connected. Please connect Z1 or Z2 device first.” Press OK.
 - Then go to the Current Device screen using the Menu.
 - It will say “No Connection. Please connect a device.”
 - Press “Find a Device”. A list of the available devices will appear. Select your device. The numbers correspond to the serial number on the back of the device.
 - After you select the device, it will ask for the Z1/Z2 password.
 - Press “Forgot Password” to reset the password.
 - Enter your new password on the following screen. You will then have 20 seconds to confirm the update on the Z1/Z2 by pressing and holding the power button on the Z1/Z2.
- If you are connected, you will see “Nitelog. Do you want to start syncing device?” Select “Yes” to start syncing the data in your Z1 or Z2 to your Nitelog App. Select “No” if you do not want to import new data.
- You will see “Sync Completed” when the process is completed. Press OK.



Buttons on Data Screen

	Download data from device	Sync with Cloud	Delete data from this phone
	Downloads all of the sleep data stored in your Z1/Z2 to the Nitelog App on your mobile device	Uploads your sleep data from your Z1/Z2 to the secure Cloud server, for storage* so you can retrieve it later. Note: data rates from your mobile carrier may apply. To avoid using the mobile data plan, switch on the “Sync Data on Wi-Fi Only” at the top of the screen.	Deletes all sleep data from the mobile device. This does not delete the data on the Z1/Z2 or in the Cloud.
		*See Terms & Privacy for security details.	

Goals

Setting Sleep Goals

Nitelog allows you to set sleep goals and track your progress towards meeting your goals. To set your personal goals, select the Menu icon in the upper left hand corner and go to Goals.

1. Press on the green box with the number in it to set the number of hours you would like to sleep as a goal.
2. Scroll to select the number of hours. Press Done to save.

AH Index

Nitelog can also track the quality of your sleep by calculating your AHI. AHI is the Apnea Hypopnea Index, in other words, the average number of apnea and hypopnea events. It is calculated by taking the total number of apnea and hypopnea events that occurred during your sleep and dividing it by the number of hours slept.

i Example: If you had a total of 24 events during the course of 8 hours of sleep, your AHI would be 3.

The lower the AHI, the better the quality of your sleep. Press on the green box with the number in it to set the number of hours you would like to sleep as a goal.

3. This section explains what the AH Index emojis mean on your Dashboard.

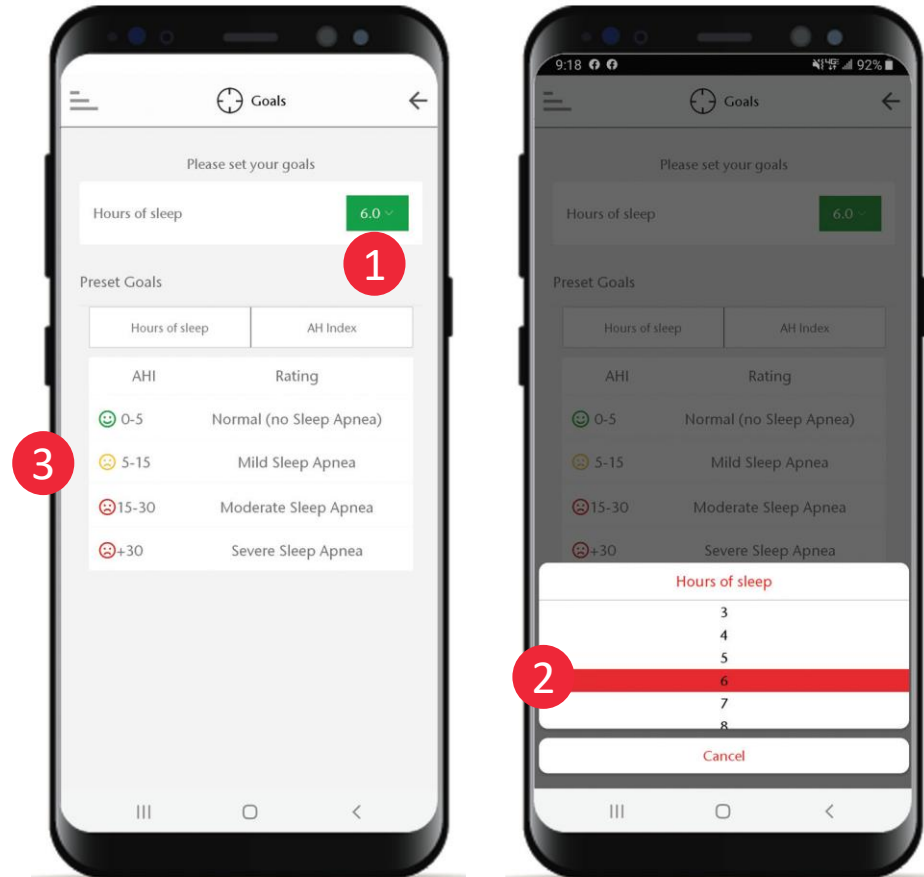
AHI < 5 is normal sleep

AHI = 5-15 is mild sleep apnea

AHI = 15-30 is moderate sleep apnea

AHI > 30 is severe sleep apnea

i Note: Individual sleep goals vary. Discuss with your physician what your sleep goals should be.



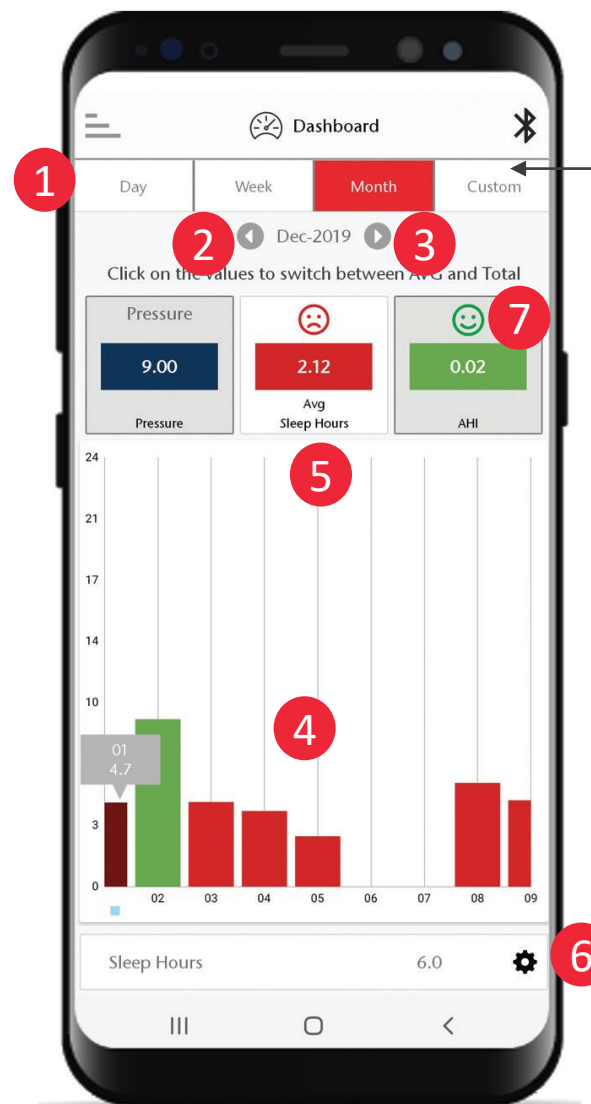
Dashboard

Sleep Data on the Dashboard

The Dashboard displays your sleep data in graphical form.

1. The buttons at the top let you switch the data range you are viewing from a single day, week, month or a custom range. Press the Day / Week/ Month/ Custom button to switch between them.
2. The date that corresponds to the data is in the middle below the buttons.
3. Use the arrow (< >) buttons to change the date range in view.
4. The chart below is a graphical representation of the sleep data. Green shows where you met your sleep goals and red is where you did not meet the goal.
5. Press the Sleep Hours value to switch between Average and Total Sleep Hours.
6. Your personal sleep goal is at the bottom of the screen. To change it, press the gear button.
7. AH Index emojis are displayed to show the quality of your sleep based on the AHI of the period displayed. The [Goals screen](#) explains what the emojis mean.

i Note: If no data is showing up or you are missing data in the Dashboard, adjust the Sleep Start Time in the [User Settings](#) to before your normal sleep time.



The color of the Bluetooth symbol indicates whether the mobile device is connected to the Z1/Z2 by Bluetooth.

Blue is connected.

Grey is disconnected.

Current Device

Settings

1. Press Settings to get to the Settings screen. The Settings screen displays the programmed settings of the current device. It also allows you to directly change the programmed comfort settings.
2. Treatment Mode – displays whether the device is programmed as a fixed pressure “CPAP” or auto-adjusting “APAP”. The treatment mode is not adjustable by a patient. Please contact your sleep therapist if you would like to change this setting. Note: APAP mode is only available on the Z1/Z2 Auto not on the Z1/Z2 CPAP.
3. Z-Breathe – Press the down arrow next to the setting. Scroll to the desired Z- Breathe setting. Press “Done” to save the setting to your device.
4. Auto Start – Slide the button to turn on or off the Auto Start/Stop mode on the Z1/Z2 device. (Auto Start/Stop may not be available on some older Z1 models).

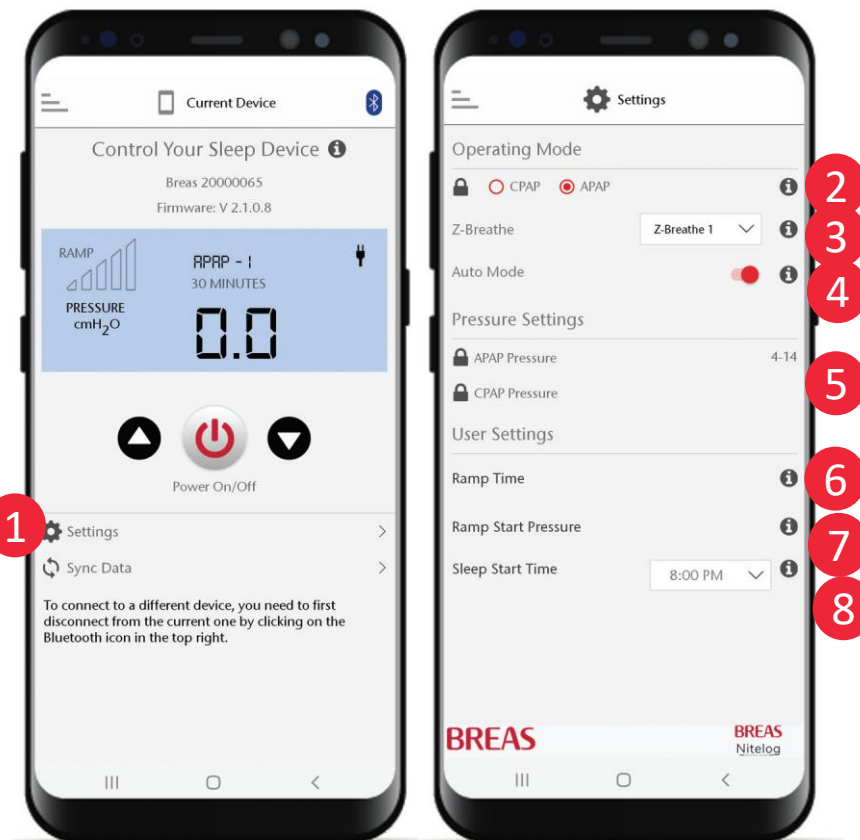
Pressure Settings

5. APAP or CPAP Pressure – Displays the current pressure programmed in the device. The pressure setting is not adjustable by the patient. Contact your sleep therapist if you want the pressure changed.

User Settings

6. Ramp Time – Press the down arrow to pull down the ramp time. Scroll to change the ramp time. Press “Done” to save the setting to your device. Note: Ramp is not used in Auto CPAP mode.
7. Ramp Start Pressure – Press the down arrow next to the ramp start pressure. Scroll to change the ramp start pressure. Press “Done” to save the setting to your device. Note: Ramp is not used in Auto CPAP mode.
8. Sleep Start Time – Adjust the sleep start time to coincide with when you usually start to go to sleep. This time will be the beginning of the window of data that Nitelog is displaying. Press the down arrow to pull down the Sleep Start Time. Scroll to change the time. Press “Done” to save the setting to the device.

i Note: If no data is showing up or you are missing data in the Dashboard, adjust the Sleep Start Time to before your normal sleep time.



Current Device (contd.)

To Control the Z1 / Z2 Auto

 The Power Button and Up and Down Arrow buttons on the Current Device screen correspond to the buttons on your Z1/Z2.


1. Press the Power Button on the mobile screen to start therapy. Press it again to stop therapy.
 2. To change the Z-Breathe setting, press and hold the Up and Down Arrow buttons at the same time on the mobile device screen. Release them when the Z-Breathe setting (APAP-1, 2, or 3 or CPAP-1, 2, 3) flashes. Use the Up or Down Arrow to change the setting.
- To save the setting, press and hold the Power Button until ACCEPT flashes. Press the Power Button quickly to cancel the change.

To Set the Ramp Time

- Press and hold the Up Arrow button on the screen until the ramp time flashes. Use the Up and Down Arrows to adjust the ramp time in 5-minute increments. The ramp will not start with a ramp time of 00 minutes. To save the setting, press and hold the Power Button until ACCEPT flashes. Press the Power Button quickly to cancel the change.

To Set the Ramp Start Pressure

- Press and hold the Down Arrow on the screen until the Ramp Start Pressure flashes. Use the Up and Down Arrow buttons on the screen to adjust the pressure. Press and hold the Power button until ACCEPT flashes. Press the Power button quickly, if you decide to cancel rather than save the change.

 **Note:** the Ramp Start Pressure must be lower than the pressure setting of your prescription or there is no benefit to the ramp. If you are using an Auto CPAP and your prescription is 4-20, there is no reason to set a ramp since the pressure will start at the lowest pressure available.

Sync Data

3. Press the Sync Data button to automatically sync the data on the Z1/ Z2 device with Nitelog. It takes you to the Data screen where you can also [Sync with the Cloud or Delete Data](#) from the phone.



Profile


The Profile screen shows the data associated with the current device.

This is the information that was entered when you first logged in and connected the Z1/Z2 with Nitelog. The first four lines will also appear in the Compliance Report.

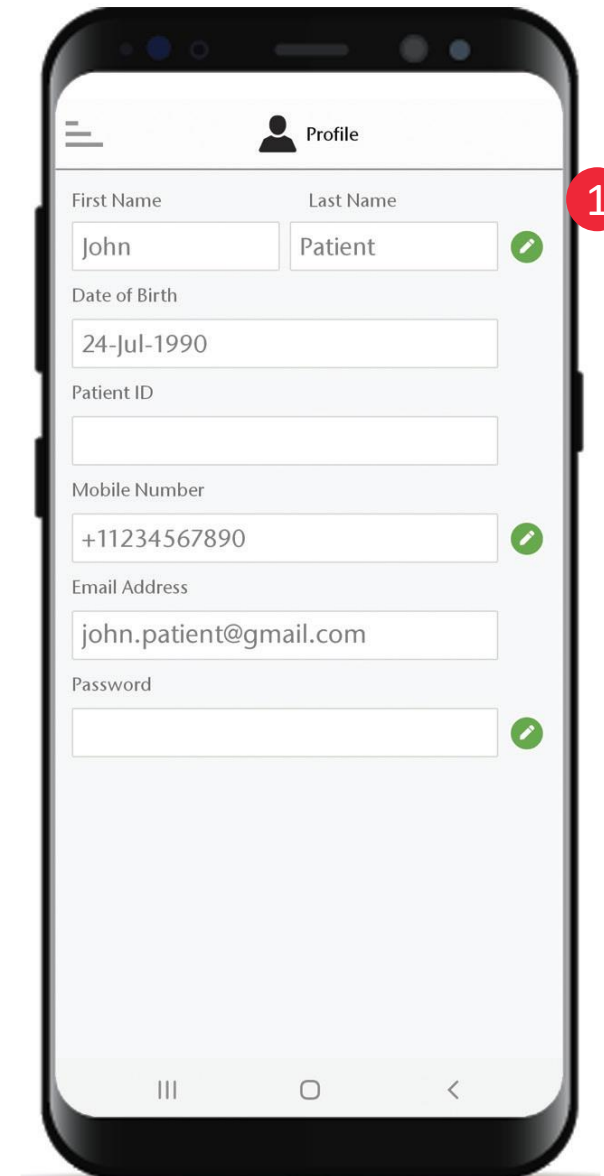
Edit Profile or Change Password

1. Press the green pencil next to the line to edit the information.

Note: you can only change your First Name, Last Name and Mobile Number. The Date of Birth, Patient ID and Email Address are fixed based on the original entry when you set up your profile.

 Press the field under First Name, Last Name and Mobile Number to edit the fields.

After you have edited all the fields, press SAVE to save the information and return to the completed Profile page.



The screenshot shows a smartphone screen with the 'Profile' app. At the top, there is a hamburger menu icon and a 'Profile' header with a person icon. The form contains the following fields:

- First Name:** John
- Last Name:** Patient (with a green pencil icon and a red circle with the number 1 next to it)
- Date of Birth:** 24-Jul-1990
- Patient ID:** (empty field)
- Mobile Number:** +11234567890 (with a green pencil icon)
- Email Address:** john.patient@gmail.com
- Password:** (empty field with a green pencil icon)

At the bottom of the screen, there are three navigation icons: a hamburger menu, a square, and a back arrow.

Compliance Report

The Compliance Report screen allows you to generate a Compliance Report to send to your doctor, insurance company or employer to demonstrate adherence on the conditions they have set regarding your CPAP usage.

Report End Day

1. Press the day field to set the day when the report ends. Swipe up or down to scroll to the correct date.

i Note: the date format is Day/Month/Year.

Compliance Range (Days)

2. Press the number field to set the number of days that you want the report to cover. Scroll up or down to adjust the number of days. Press “Done” to save.

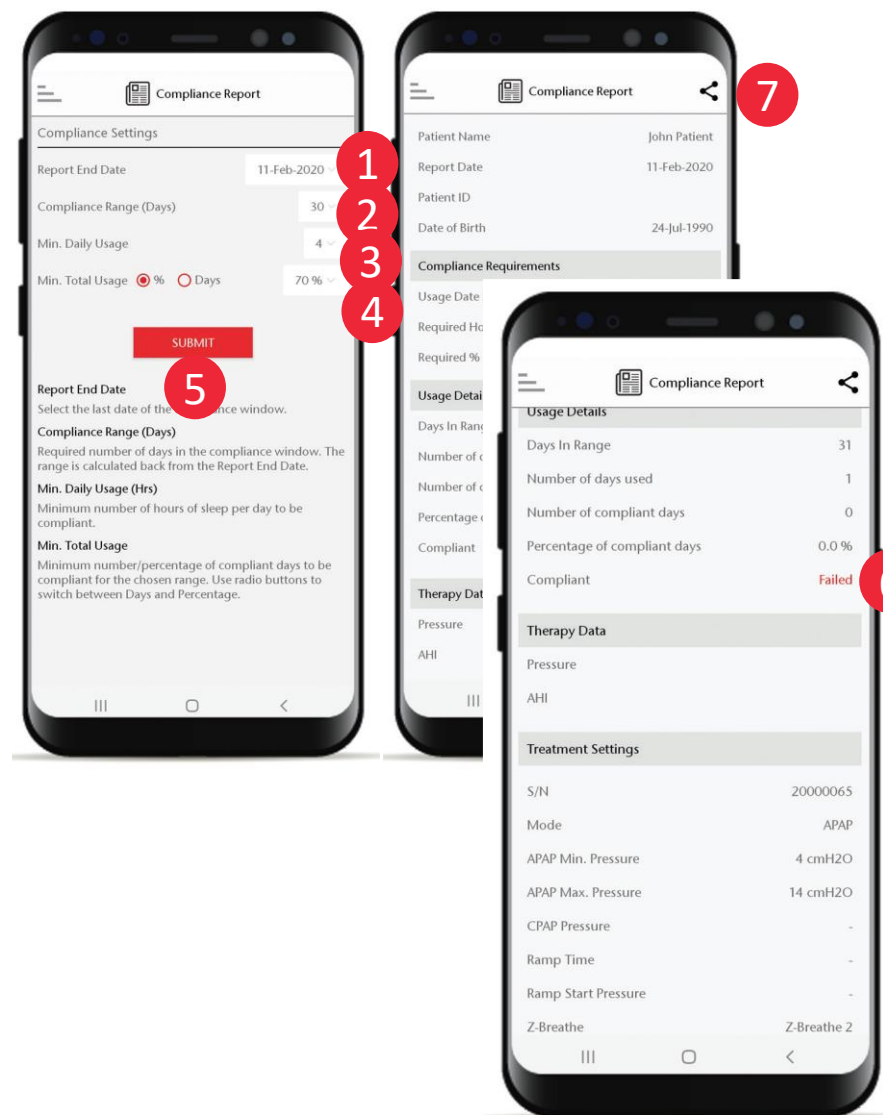
Min. Daily Usage (Hours)

3. Press the number field to set the minimum number of hours of sleep required to meet the compliance conditions. Scroll up or down to adjust the number of hours. Press “Done” to save.

Min. Total Usage

4. Press the number to set the minimum number or percentage of days needed to in order to meet the compliance conditions. Scroll up or down to the adjust the number. The circle to the left of % or the number indicate whether this is a percentage or a number. Press the circle to switch from percentage to number.

- Example: Some reimbursement guidelines require that the patient use the CPAP device 4 hours per night 70% of the days in a 30-day period in order to be compliant.
5. Once you have set the values, press SUBMIT to generate the report.
 6. The report summarizes the sleep data based on the compliance settings. At the bottom of the Usage Details, it indicates whether you passed or failed at meeting the compliance conditions.
 7. Press the button at the upper right of the screen to SEND the report via email or PRINT the report to a connected printer.



Compliance Report

Compliance Settings

Report End Date: 11-Feb-2020

Compliance Range (Days): 30

Min. Daily Usage: 4

Min. Total Usage: ☒ % ☐ Days 70 %

SUBMIT

Compliance Requirements

Patient Name: John Patient

Report Date: 11-Feb-2020

Patient ID:

Date of Birth: 24-Jul-1990

Usage Details

Days In Range	Number of days used	Number of compliant days	Percentage of compliant days
31	1	0	0.0 %

Compliant Failed

Therapy Data

Pressure:

AHI:

Treatment Settings

S/N: 20000065

Mode: APAP

APAP Min. Pressure: 4 cmH2O

APAP Max. Pressure: 14 cmH2O

CPAP Pressure: -

Ramp Time: -

Ramp Start Pressure: -

Z-Breathe: Z-Breathe 2



Understanding the Compliance Report

Compliance Requirements

- Usage Date Range – The days for which the compliance report is being run.
- Required Hours Per Day – The number of hours of therapy required per day to be compliant.
- Required % of Compliant Days – The percentage of days of therapy in the date range that are required for compliance.

Usage Detail

- Days in Range – The number of days within the date range.
- Number of Days Used – The total number of days of therapy within the date range.
- Number of Compliant Days – The number of days within the range with the minimum hours of therapy.
- Percentage of Compliant Days – Percentage of days within the date range which meet the minimum hours of therapy.
- Compliant Pass / Fail – Shows whether the amount of therapy passes or fails the compliance requirements.

Therapy Data

- Pressure Average – Average of the 95th percentile pressure values that is delivered during the compliance period.
- AHI (Apnea Hypopnea Index) – AHI is the total number of Apnea/Hypopnea events divided by the number of hours in the therapy time.
- AHI Average – Average AHI during the compliance period.

Treatment Settings (Date of Report)

- S/N – Serial number of the Z1/Z2
- Mode – CPAP or APAP
- Min/Max pressure – Minimum/Maximum pressure setting for the APAP range.
- CPAP pressure – Programmed therapy pressure.
- Ramp Time – Length of time the ramp is set for.
- Ramp Start Pressure – Starting pressure of the ramp.
- Z-Breathe – Current Z-Breathe setting - CPAP/APAP -1, 2, 3.



Other Menu Items

Help

Press the Help button to connect directly to the Nitelog User Guide online.

About

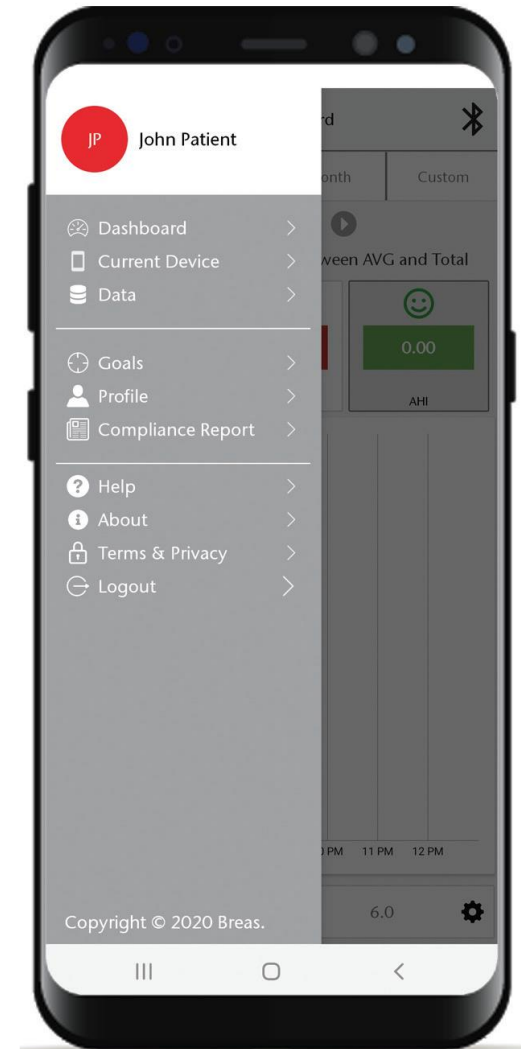
Press About to display information about the Nitelog User Manual and Z1/Z2 CPAP Devices.

Terms & Privacy

Press Terms & Privacy to display the Software End-User License Agreement.

Logout

Press Logout to logout of the Nitelog app. If you logout, your Nitelog data will be deleted on your mobile device. You will need to sync with the Z1/Z2 CPAP or the Cloud to view your data on your mobile device.





Notes:

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