Alice NightOne

User Manual

PHILIPS

RESPIRONICS

© Koninklijke Philips N.V., 2018. All rights reserved.

Intended Use

The Alice NightOne is a physiological data recorder intended to collect and record data from multiple physiological channels. It is intended for use by or on the order of a physician. The Alice NightOne is intended for use in a supervised (hospital) or unsupervised (home) environment.

Caution: *US federal law restricts this device to sale by or on the order of a physician.*

Warnings

- The Alice NightOne device should be worn over clothing.
- Consult with your physician prior to performing the study if you have a cardiac pacemaker or implantable cardiac defibrillator.
- All cables and sensors (applied parts) must be removed before performing cardiac defibrillation. The Alice NightOne device and accessories are not protected against the effect of cardiac defibrillation
- If the device appears damaged or the enclosure is broken, discontinue use and contact your provider for assistance.
- If you notice any unexplained changes in the performance of this device or if the device is dropped or mishandled, discontinue use and contact your provider for assistance.
- Use only accessories that have been approved by Philips Respironics.
- When attaching the sensors and cables, be careful to route the cables in a manner that will reduce the possibility of strangulation, discomfort, or the sensors becoming detached.
- Batteries may pose a choking hazard. Do not let children handle batteries.

Cautions

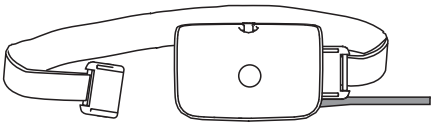
- Do not place liquids on or near the device while the battery door is open. If liquids are spilled on the device, contact your provider for assistance.
- Do not immerse the device in any fluids.
- Repairs and modifications must be performed by Philips Respironics-authorized service personnel only. Unauthorized service could cause injury, invalidate the warranty, or result in costly damage.
- Condensation may damage the device. If the device has been exposed to either very hot or very cold temperatures, allow it to adjust to room temperature (operating temperature) before starting therapy. Do not operate the device outside of the operating temperature range (41°F to 95°F (+5°C to +35°C)).

Security Measures Regarding ePHI (Electronic Personal Health Information)

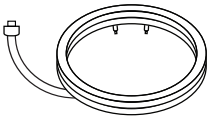
ePHI stored on the Alice NightOne is encrypted with a FIPS 140-2 compliant algorithm.

Package contents

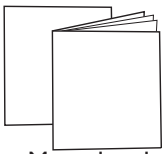
Within the Alice NightOne carrying case given to you by your provider, you will find:



Alice NightOne Device
(with attached effort belt and SpO_2 sensor)



Nasal Cannula

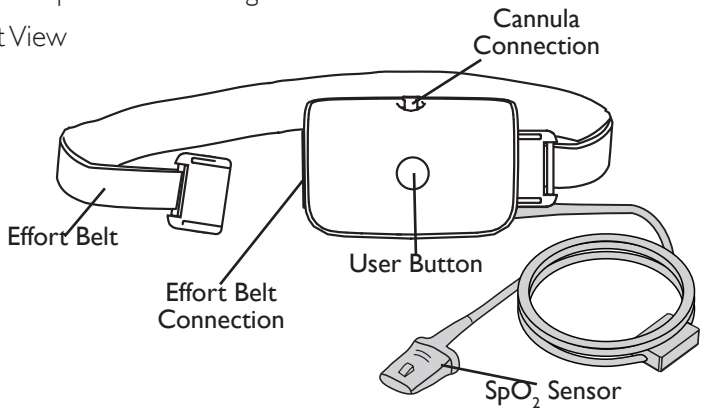


User Manual and
Quick Start Guide

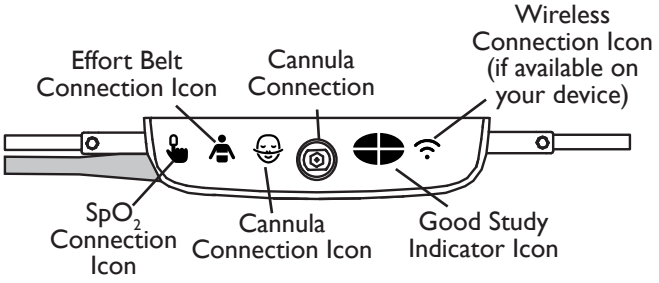
Alice NightOne Overview

Alice NightOne is intended as a diagnostic device for adults. No physiological alarms are present. Alice NightOne is not a monitor.

Front View



Top View



Alice NightOne is not made with natural rubber latex.

Symbols Glossary

Icon	Title and Meaning	Reference
	Operator's manual; operating instructions Consult instructions for use.	IEC 60878 ISO 7000-1641 Symbol 5.4.3, ISO 15223-1
IP22	Drip proof equipment Protection against ingress of solid foreign objects ≥ 12.5 mm diameter. Protection against ingress of water with harmful effects dripping (15° tilted).	-
℞	Prescription device Caution: U. S. federal law restricts this device to sale by or on the order of a physician.	-
	Type BF applied part To identify a type BF applied part complying with IEC 60601-1.	IEC 60878 IEC 60417-5333
	Non-ionizing electromagnetic radiation Indicates that the equipment includes RF transmitters.	IEC 60878 IEC 60417-5140
	USB (Universal Serial Bus) Port Indicates a connector for USB connection.	-

REF	Reorder number Indicated the manufacturer's catalogue number so the medical device can be identified.	ISO 7000-2493 Symbol 5.1.6, ISO 15223-1
SN	Serial number Identify the manufacturer's serial number for the medical device.	IEC 60878 ISO 7000-2498 Symbol 5.1.7, ISO 15223-1
#	Model number To identify the model number or type number of a product.	IEC 60878 IEC 60417-6050
	Manufacturer Indicates the medical device manufacturer.	IEC 60878 ISO 7000-3082 Symbol 5.1.1, ISO 15223-1
	Date of manufacture Indicates the date when the medical device was manufactured.	IEC 60878 ISO 7000-2497 Symbol 5.1.3, ISO 15223-1
	Temperature limit Indicates the storage temperature limits to which the medical device can be safely exposed.	IEC 60878 ISO 7000-0632 Symbol 5.3.7, ISO 15223-1
%	Humidity limitation Indicates the range of humidity to which the medical device can be safely exposed.	IEC 60878 ISO 7000-2620 Symbol 5.3.8, ISO 15223-1
	Keep dry Indicates the medical device that needs to be protected from moisture.	IEC 60878 ISO 7000-0626 Symbol 5.3.4, ISO 15223-1
	Fragile, handle with care Indicates the medical device can be broken or damaged if not handled carefully.	IEC 60878 ISO 7000-0621 Symbol 5.3.1, ISO 15223-1
	This way up Indicates correct upright position of the transport package.	IEC 60878 ISO 7000-0623
	SpO_2 Sensor Connection Icon	-
	Effort Belt Connection Icon	-
	Cannula or CPAP Mask Connection Icon	-
	Good Study Indicator	-
	Wireless Connection to a Therapy Device Icon (if available on your device)	-

Standards Reference

ISO 7000:2014, Graphical symbols for use on equipment – Registered symbols
ISO 15223-1:2012, Medical devices—Symbols to be used with medical devices labels - General requirements
IEC 60417:2002 DB, Graphical symbols for use on equipment
IEC/TR 60878:2015, Graphical symbols for electrical equipment in medical practice

Icons

The following icons may be displayed on the top of the device. Each icon is associated with a sensor or device connection, except for the Good Study Indicator. The icons are displayed to guide sensor application or to show sensor or device status.

The icon status is displayed based on the associated connection.

Icon Status	Definition
Solid Green	The connection has been made, and the device is getting a good signal.
Flashing Yellow	The associated sensor needs to be connected, or the device is not getting a good signal and the current connection needs to be adjusted. Try removing and reapplying the sensor or adjusting the sensor placement until the icon appears solid green. **Note:** *It may take a few breaths before the device detects a good signal.*
Successful Setup Indication	After the guided setup is complete, all icons will be displayed solid green and, after about 1 minute, will individually turn off in the following order: SpO_2 icon, effort belt icon, cannula icon, and then each section of the Good Study Indicator. This indicates all necessary sensors have been applied successfully and the device is getting a good signal from all necessary connections.

Icon	Definition	Icon	Definition
	SpO_2 Sensor Connection Icon		Good Study Indicator (see below)
	Effort Belt Connection Icon		Wireless Connection to a Therapy Device Icon (if available on your device)
	Cannula or CPAP Mask Connection Icon		

Good Study Indicator

The Good Study Indicator displays how much good quality data the device has gathered for an amount of time set by your provider. To view the Good Study Indicator at the end of a study, first check that the device has stopped recording. Look inside the SpO_2 sensor. If the red light is on, the Alice NightOne is still in recording mode. To exit recording mode and end the study, press and hold the User Button until the Good Study Indicator flashes.

Once the device has exited recording mode, wait at least 1 minute. Then, briefly press (less than 5 seconds) and release the User Button again and the Good Study Indicator will be displayed.

Important: *The Good Study Indicator can only be checked at the end of a study. Pressing and holding the User Button while a study is in progress will end the study and turn the device off.*

Good Study Indicator Status

Icon	Definition	Icon	Definition
	The device has gathered 25% of the good quality data requested by your provider.		The device has gathered 75% of the good quality data requested by your provider.
	The device has gathered 50% of the good quality data requested by your provider.		The device has gathered 100% of the good quality data requested by your provider.

Preparing for a Sleep Study

The Alice NightOne device will automatically power on and begin recording when the effort belt is connected. The device can also be manually powered on by pressing and holding the User Button until the Good Study Indicator flashes. Powering on the device will also initiate the device's guided setup to help you apply the appropriate sensors and connections.

When you are ready to go to bed, simply attach the sensors as described in the following section.

Attaching the Sensors

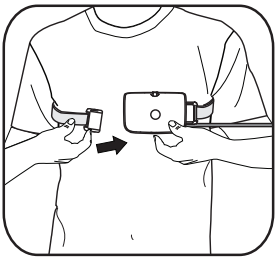
Warning: *The Alice NightOne device should be worn over clothing.*

1. Effort Belt

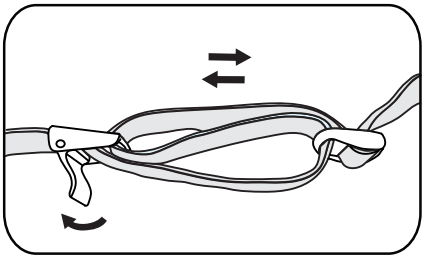
Place the effort belt around your chest so that the Alice NightOne device is in the center of your chest and the belt is evenly aligned with both nipples, or a few inches below, if that is more comfortable. Adjust the length of the effort belt so that before it is stretched, the loose end is about one hand-width from the device.

Insert the loose end of the effort belt into the effort belt connection slot on the side of the device. This will automatically power on the device, begin the recording, and start the guided device setup.

Adjust the belt to fit. It should be snug, but not uncomfortable. After several breaths with the belt connected, the effort belt icon () will stop flashing yellow and turn green. If the icon does not turn green, check the position and snugness of the belt.



Effort Belt Connection



Effort Belt Adjustment

2. Cannula or Face Mask Connection

Your provider may choose for you to wear a cannula or a face mask connected to your CPAP therapy device.

Cannula Connection

If it is not already connected, connect the nasal cannula to the cannula connection port on the device.

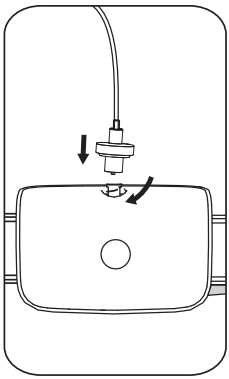
Warning: *When attaching the sensors and cables, be careful to route the cables in a manner that will reduce the possibility of strangulation, discomfort, or the sensors becoming detached.*

Place the cannula tube behind your ears and route it under your chin. Make sure the cannula sensor prongs are facing up and placed inside your nostrils.

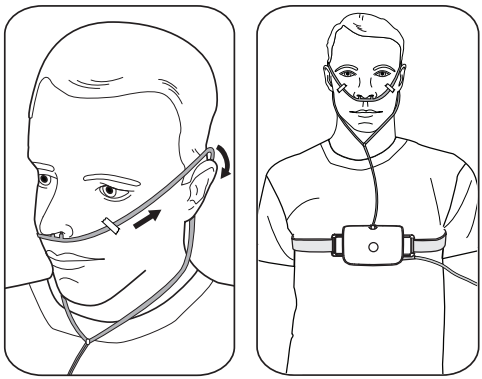
Note: *Your provider may have included medical tape with the Alice NightOne device. If so, you can use it to secure the cannula on your face by placing a small piece of tape on both cheeks.*

Then, slide the adjuster on the tube up to your chin until secure as shown. After several breaths with the cannula properly in place, the cannula icon ( ) will stop flashing yellow and turn green. If the icon does not turn green, make sure the cannula sensor prongs are inside your nostrils. Breathe through your nose for ten seconds, and check the icon again.

Important! *The cannula is single use only.*



Cannula Connection



Cannula Placement

Face Mask Connection

If your provider has asked you to use your therapy device with Alice NightOne, turn on your therapy device and ensure that the blower is on. Then, put on your mask so that it fits comfortably without leaking as you normally would. For more information, refer to the instructions provided with your mask or therapy device.

After several breaths with the mask properly in place and the blower on, the cannula or CPAP mask connection icon ( ) will stop flashing yellow and turn green. If the icon does not turn green, make sure the mask is properly fitted and your therapy device's blower is on. Breathe for ten seconds, and check the icon again.

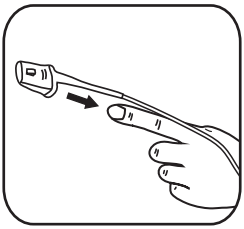
After the initial connection, the cannula or CPAP mask connection icon will begin flashing yellow again, until the Alice NightOne detects a good signal from the therapy device. If the icon does not turn green, make sure the mask is properly fitted and your therapy device's blower is on. Breathe for ten seconds, and check the icon again.

3. SpO_2 Finger Sensor

Attach the SpO_2 finger sensor on to your forefinger as recommended by your provider, and route the sensor wire over the back of your hand.

After several breaths with the finger sensor properly in place, the SpO_2 icon ( ) will stop flashing yellow and turn green. If the icon does not turn green, check the position of the sensor and make sure it is securely in place.

Note: *Your provider may have included medical tape with the Alice NightOne device. If so, you can use it to secure the SpO_2 sensor to your hand by first making a fist, and then placing tape over the wire on the back of your hand.*



SpO_2 Finger Sensor Connection

Note: *If you need any additional assistance setting up or using the device, contact your provider.*

Wireless Connection to a Therapy Device

If your provider has configured your Alice NightOne device to communicate wirelessly with your Philips Respironics therapy device, the two devices will automatically pair and connect when both ends of the effort belt are attached to the Alice NightOne device and your therapy device is within range.

Note: *The wireless connection icon ( ) on the Alice NightOne will be solid green.*

If your devices do not automatically connect, the wireless connection icon ( ) on the Alice NightOne device will flash yellow or may not appear at all. Make sure:

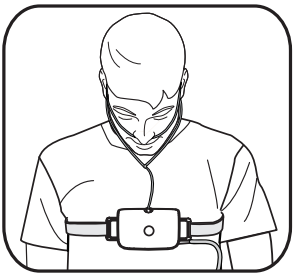
- your therapy device is turned on.
- your therapy device is within range.

If the devices still do not connect after checking and/or correcting the items above, the devices may need to be reconfigured by your provider. Contact your provider for further assistance.

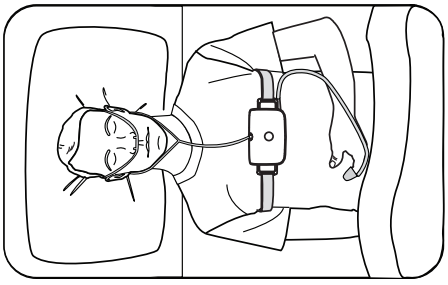
Starting the Study

Once all of the sensors have been connected and the device is getting good signals from all of them, all icons will be displayed solid green and, after about 1 minute, will individually turn off in the following order: SpO_2 icon, effort belt icon, cannula icon, and then each section of the Good Study Indicator.

This means that the device has begun recording, and you may now go to sleep.



Check Icon Status



Ready to go to Sleep

Checking the Sensor Status

The User Button allows you to check the status of the sensors any time during the course of the study.

To check the sensors, press and release the User Button. The sensor icons will be displayed according to the sensor status. A solid green icon will appear for a good connection, and a flashing yellow icon will appear for a connection that is loose or missing.

Ending the Study

When you wake up in the morning, press and hold the User Button until the Good Study Indicator flashes to end the study and stop the device's recording. Wait at least 1 minute. Then, quickly press and release the User Button, and the Good Study Indicator will be displayed. Make note of the status of the Good Study Indicator. Your provider may ask you for this information.

Carefully, remove the sensors and the Alice NightOne device. Dispose of the cannula. Place the rest of the sensors and the device into the carrying case and return to your provider as instructed.

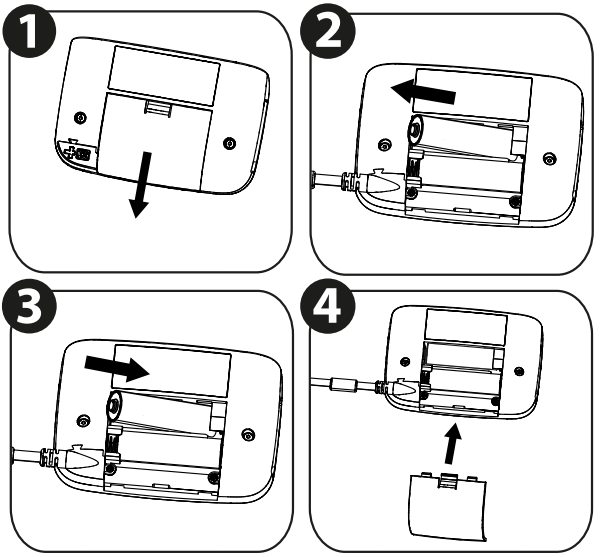
Changing the Batteries

If requested by your provider, you made need to change the batteries in the Alice NightOne device.

Note: *The patient is an intended operator.*

To change the batteries:

1. Remove the battery cover on the back of the Alice NightOne device.
2. Remove used batteries and dispose of in accordance with local regulations.
3. Insert the new batteries so that their positive (+) ends match those shown in the diagram in the bottom of the battery chamber.
4. Replace the battery cover.



Changing the Batteries

Respironics Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668 USA

REF 1113330

1113330 R02
JDW 12/05/2018