RESPIRONICS

Alice® *PDx*™

PROVIDER MANUAL

RESPIRONICS®
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1. Introduction

Alice*PDx* is a portable, diagnostic recording device. It may be used for obstructive sleep apnea screening as well as for follow-up and diagnostic assessment. The device may be used in a sleep lab or clinical setting by trained professionals, and it may be used at home by patients as directed by their healthcare provider.

The **Alice***PDx* device is capable of recording various physiologic inputs and storing the data locally on the removable storage card. The device may also be connected directly to a computer running the Sleepware software application. Sleepware can display live or pre-recorded data in a resolution consistent with the computer hardware specifications.

Intended Use

The **Alice***PDx* is a multi-function recording device that collects and stores physiological signals. The recorded data is downloaded, presented graphically on a computer screen, and may be printed for diagnostic review by clinicians/physicians to aid in the diagnosis of respiratory sleep disorders or other physiological disorders. The **Alice***PDx* may be used on adults in the home or hospital/ institutional environment.

The device does not provide alarms and is not intended for use as an automated apnea or cardiac monitor.

Warnings and Cautions

CAUTION

U.S. federal law restricts this device to sale by or on the order of a licensed healthcare professional. This product should be used only under the supervision of a physician.

Warnings

The following warnings indicate the possibility of injury to the user or the operator.

- Consult with the patient's physician prior to performing the study when a patient has a cardiac pacemaker.
- Remove all patient cables (applied parts) before performing cardiac defibrillation. The **Alice***PDx* device and its accessories are not protected against the effect of cardiac defibrillation.
- Do not use the **Alice***PDx* device in a Magnetic Resonance Imaging (MRI) environment or in close proximity to a high emissions source.
- Do not use during high frequency surgical procedures or electrosurgery.
- The **Alice***PDx* system and software are not designed to replace the clinical judgement and analysis of a healthcare professional.
- Do not plug sensor cables into electrical outlets. Cable contact with electrical outlets presents a serious shock hazard.
- Make sure the conductive parts of electrodes and associated connectors, including the neutral electrode, do not contact other conductive parts, including earth.
- Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.
- Do not use the device in the presence of a flammable anaesthetic mixture in combination with oxygen or air, or in the presence of nitrous oxide.
- Verify all sensors are working properly prior to use.
- 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.
- Periodically inspect the sensor cables for damage or signs of wear. Discontinue use and replace if damaged.
- If you notice any unexplained changes in the performance of this device, if the device is dropped or mishandled, if water is spilled into the enclosure, or if the enclosure is broken, discontinue use and contact Respironics for assistance.
- Repairs and adjustments must be performed by Respironics-authorized service personnel only. Unauthorized service could cause injury, invalidate the warranty, or result in costly damage.
- Use caution when removing damaged batteries and avoid exposing skin to any battery leakage.
- Recycle or dispose of batteries in accordance with local regulations. Do not incinerate.

- Use only accessories that have been approved by Respironics.
- Connecting the **Alice***PDx* to a device that is not approved by Respironics with the therapy and/or Sleeplink communication cables, may result in a shock hazard to patient. Only devices that are IEC 60601-1 approved may be attached to the **Alice***PDx*.
- Ensure that any computer connected to the **Alice***PDx* complies with the safety standard IEC 60950. Only connect the **Alice***PDx* to an IEC 60950 compliant computer when configuring the device or when viewing a sleep study in real time, carefully following the respective instructions. Do not connect the **Alice***PDx* to any other USB compatible device.

Cautions

The following cautions indicate the possibility of damage to the device.

- Follow all of the manufacturer's recommendations and instructions for the **Alice***PDx* and all equipment used with the device.
- Operation of the **Alice***PDx* device may be adversely affected by:
  - electromagnetic fields exceeding the level of 10 V/m in the test conditions of EN 60601-1-2
  - the operation of high frequency (diathermy) equipment
  - defibrillators, or short wave therapy equipment
  - radiation (e.g., x-ray, CT)
  - magnetic fields (e.g., MRI)
- Synthetic fabric from draperies or rugs can also cause interference due to static electricity. Touching an inanimate object (e.g., wall) before handling the system often prevents static build-up problems.
- Strong transmitter signals from TV, radio, airport, police, fire, and ambulance stations could be received and may be misinterpreted as heart and/or breath signals. If you are located less than one mile from any of these sources, ask Respironics Customer Service to assist you in determining whether your system will operate properly.
- Do not place liquids on or near the **Alice***PDx* device. If liquids are spilled on the equipment, discontinue use until it can be determined that the device can be safely operated. Contact Respironics for assistance.
- Do not immerse the **Alice***PDx* device in any fluids.
- Performance of the **Alice***PDx* cannot be assured when connected to therapy devices not manufactured by Respironics. Hand scoring of the data must be performed to ensure a correct diagnosis.
- If you use an ExG or EEG Neuroground, do not use the right leg/ground ECG lead.
- Never use harsh cleaning agents or chemicals. Never spray cleaner directly onto the device.
- Make sure all parts are thoroughly dry before using.
- Do not autoclave, gas, or pressure sterilize **Alice***PDx* equipment.

Package Contents

The **Alice***PDx* device should include the following items. If any of these items are not included, contact a Respironics representative.

The **Alice***PDx* system contents:

- **Alice***PDx* device
- Device holster and lanyard
- Oral thermistor sensor
- Nasal cannula starter pack
- SpO_2 sensor
- SpO_2 extension cable
- Chest and abdominal effort belts and associated wire set
- PC communication cable
- Four alkaline batteries
- Removable SD data storage card
- SD card reader and extension cable
- Manuals

WARNING

Use only accessories that have been approved by Respironics.

Optional equipment:

- ECG yoke
- ExG yoke
- ECG and neurological electrodes (for ExG)
- Therapy device communication cable with SmartCard connection
- Therapy device communication cable with serial connection (typically used with ventilation devices)

Product Support

If you need product support, call the Respironics Customer Service department at 1-800-345-6443. You may also send an e-mail to Respironics Customer Service at **service@respironics.com**.

Limited Warranty

Respironics, Inc. warrants that the **Alice***PDx* device shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of two years from the date of sale by Respironics, Inc. to the customer. If the product fails to perform in accordance with the product specifications, Respironics, Inc. will pay customary freight charges from Respironics, Inc. to the customer location only. This warranty does not cover damage caused by accident, misuse, abuse, alteration and other defects not related to material or workmanship.

Respironics, Inc. disclaims all liability for economic loss, loss of profits, overhead or consequential damages which may be claimed to arise from any sale or use of this product. Some states do not allow the exclusion or limitation of incident or consequential damages, so the above limitation or exclusion may not apply to you.

This warranty is given in lieu of all other express warranties. In addition, any implied warranties—including any warranty of merchantability or fitness for the particular purpose—are limited to one year. Some states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you. This warranty gives you specific legal rights, and you may have other rights that vary from state to state.

To exercise your rights under this warranty, contact Respironics, Inc. at:

United States:
Respironics, Inc.
1001 Murry Ridge Lane
Murrysville, Pennsylvania
15668 USA
Telephone: 1-800-345-6443

Europe:
Respironics Germany
Gewerbestrasse 17
82211 Herrsching, Germany

Telephone: +49 815293060

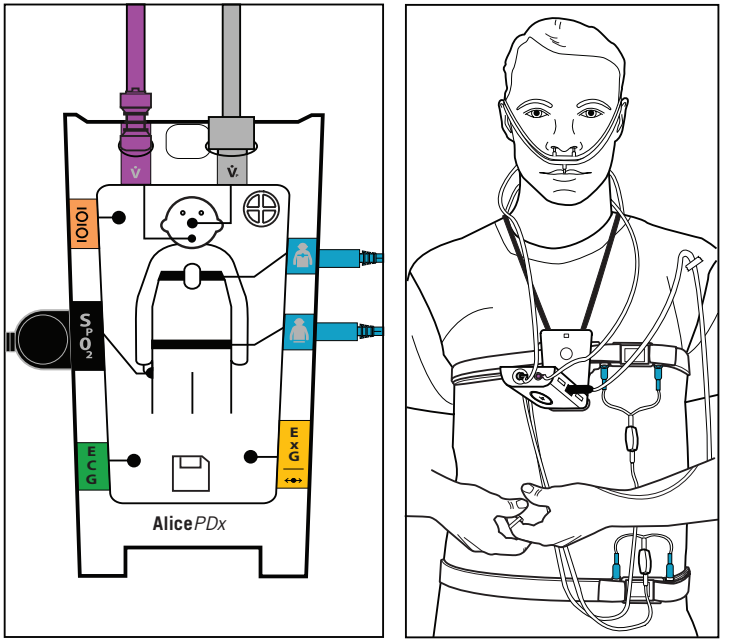
Applicability of Warranty

The terms and conditions of this warranty are applicable as between Respironics, Inc. and the customer as to either a sale of the equipment, or to a transaction whereby Respironics, Inc. sells or conveys such equipment to a third party for lease to the customer.

The limitations and warranty provision herein shall ensure the benefit of Respironics, Inc. and any manufacturer of the equipment sold by Respironics, Inc.

System Overview

The flow of data through the **Alice***PDx* system begins with sensors attached to the patient. The sensors pick up physiologic signals, such as airflow, pulse oximetry, and chest and abdominal effort. Sensor cables carry the signal to the **Alice***PDx* device. The signals are stored on the removable memory card, or, if configured to do so, the signals are sent from the **Alice***PDx* device to a computer running the Alice Sleepware diagnostic application.

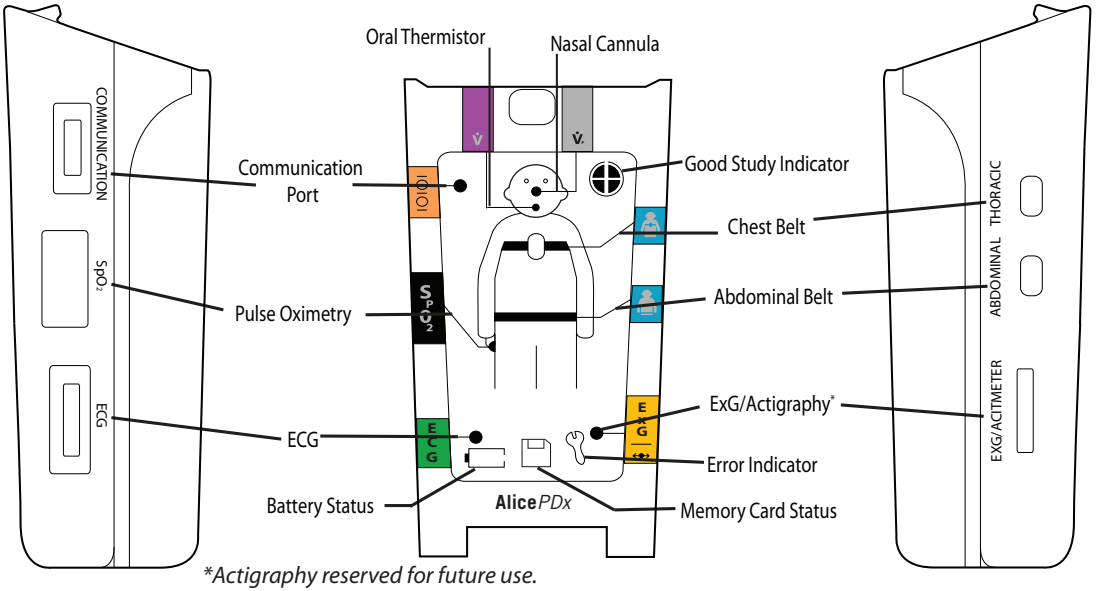


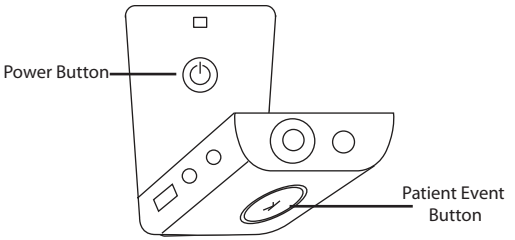
Basic set of sensors connected

The **Alice***PDx* device interface is simple and informative. The color-coded labels found around the perimeter show where to connect the various sensors. Each sensor connector is color-coded to correspond to the sensor connection on the device. In addition, the name of the sensor is located on the adjacent side of the device, as shown in the figure above. The basic sensor set includes the nasal cannula and/or the oral thermistor, abdominal and chest effort belts, and the SpO_2 sensor. Each of the sensors has a corresponding connection indicator on the **Alice***PDx* screen. These indicators will flash to show which sensors your healthcare provider has programed to be recorded. Once each connection is made, the indicators will stop flashing to show a good connection.

In addition to the basic channel set indicators, there are also indicators for ECG and ExG yokes. When the study is configured for ECG and ExG, the respective yoke indicator displays a flashing connection ( ) symbol until the associated yoke is plugged in. When the yoke is plugged in, the indicator stops flashing and turns solid.

Other visual indicators include the Good Study Indicator, the battery and memory card status, and device-level error. All of the symbols used in the interface are defined in the *Symbol and Label Definitions* section.





Alice*PDx* device interface

Device buttons

Good Study Indicator

The Good Study Indicator displays how much good quality data is needed for a complete study. In order to conduct an effective Sleep Apnea study, patient airflow and pulse oximetry are the most important variables. Without either of these signals, the sleep study would be declared diagnostically invalid for insufficient data. The Good Study indicator prevents this from occurring.

The indicator measures both patient airflow, gathered by the nasal cannula and/or the oral thermistor, and pulse oximetry, gathered by the SpO_2 sensor, and decides if the signals read are true signals of good quality. Combining these factors with the amount of time allotted for the study, the Good Study Indicator determines the amount of good quality data gathered and displays the amount in 25% increments on the **Alice***PDx* display screen.

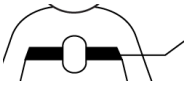
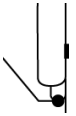
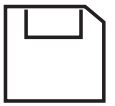
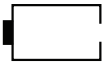
As a result, the patient can see how much good quality data was gathered after waking and convey this information to the heathcare provider. Then, the healthcare provider can determine if the patient needs to repeat the study.

Symbol and Label Definitions

Symbols			
Symbol	Definition	Symbol	Definition
	Consult accompanying documents		Type BF Applied Part
	Prescription (Rx) only		Canadian/US Safety Certification
	Power Button		Patient Event Marker (PEM) sets an event marker during recording

Sensor Connection Labels			
Symbol	Definition	Symbol	Definition
	Label for oral thermistor connection		Label for nasal cannula connection
	Label for chest belt connection		Label for abdominal belt connection
	Label for ExG / Actigraphy connection		Label for ECG connection
	Label for pulse oximetry connection		Label for PC and therapy device connection

Display Icons and Connection Indicators

Symbol	Definition	Symbol	Definition
	Indicates good connection for either the ECG, ExG, or serial connections		Indicates thermistor (ORAL) connection
	Indicates cannula (NOSE) connection		Indicates chest belt (THO) connection
	Indicates abdominal belt (ABD) connection		Indicates SpO_2 connection
	Indicates a device error Contact Respironics for assistance		Indicates sleep study has not begun or the device has gathered less that 25% good quality data needed for a complete study
	Indicates the device has gathered 25% good quality data needed for a complete study		Indicates the device has gathered 50% good quality data needed for a complete study
	Indicates the device has gathered 75% good quality data needed for a complete study		Indicates the device has gathered 100% good quality data needed for a complete study
	Indicates memory card is full (will flash until replaced)		Indicates memory card is empty, (will flash if missing or corrupted)
	Indicates battery is empty		

Note: *Connection symbols will flash when they do not detect a good connection.*

2. Software Installation

This chapter provides a brief overview of the software installation. Before you can view waveform data collected from an **Alice***PDx* device, you must install the Sleepware software on a computer.

Installing Sleepware

Before installation, please note the following:

1. You must be logged onto the computer as "Administrator."
2. Ensure that all folders to be used by specific groups and users have the necessary permissions settings.
3. The permissions on all data locations must be opened so that all users have read and write access. The software installer will attempt to do this for the chosen installation folder.
4. Insert the Sleepware CD into the CD drive of your computer and follow the on-screen instructions.
5. After installation is complete, create all of the data locations needed (see Sleepware's online help for details). As Administrator, change the security rights attached to any other data locations you've created, to allow all users full control of these directories. You can also change the user type back to "restricted" on the computer if necessary.

Note: *For more advanced functionality, such as Windows Terminal Services, refer to the Sleepware online help.*

Note: *When you change access permissions on a folder, Windows prompts you with a choice of either applying changes to "this folder only" or to "this folder, subfolders, and files." Choose the second option to apply changes to all of the folders/files.*

Adding an Alice*PDx* Device to Sleepware

You must add a new **Alice***PDx* device to Sleepware before it can be used:

1. Click on the **Configure** button on the Sleepware starter bar and select the **Add/Modify Device** option from the pop-up menu.

The Add/Modify Device menu is displayed.

2. Select the **AlicePDx** option.

   The **Alice***PDx* Add/Modify Device window is displayed.

3. Click the **Enable support for AlicePDx** check box and enter a **Friendly name** (a name that is recognizable to you) for the **Alice***PDx* device.

   The name you enter will appear on the Sleepware starter bar as a device button.

4. Click **OK** to complete the device addition.

Refer to Sleepware's online help for instructions on how to configure an **Alice***PDx* device for use with Sleepware.

3. Alice*PDx* Device Setup

This chapter describes how to set up the **Alice***PDx* device for use with a patient.

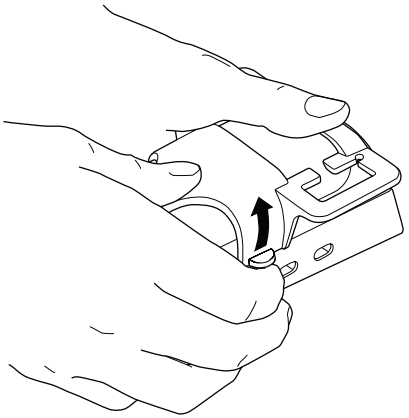
Installing Batteries and SD Memory Card

The **Alice***PDx* device can be powered by three, 1.5V, AA-size alkaline or three, 1.5V, AA-size NiMH rechargeable batteries. It is highly recommended that fresh batteries be installed prior to use for each night of a sleep study.

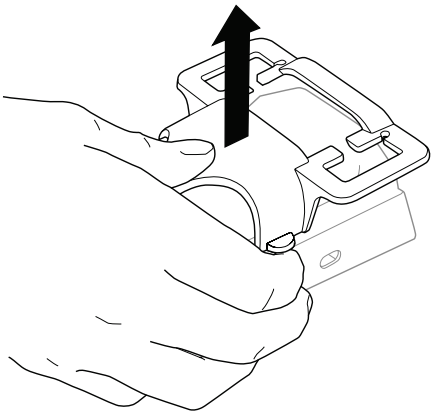
To remove the plastic holster from device:

1. Hold the **Alice***PDx* device in one hand, with the back of the device facing you.
2. With your opposite hand, place your thumb in the center of the back and your finger on the small tab on the side of the device.
3. While pressing down with your thumb, slowly pull back with your fingers until the tab snaps loose, and the holster is removed.

Note: *Removing the holster may be difficult. Use care not to damage the holster or the device.*



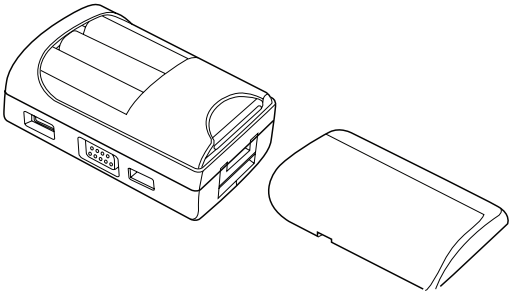
Lift small tab up



Lift until holster snaps loose

To install batteries and memory card in the device:

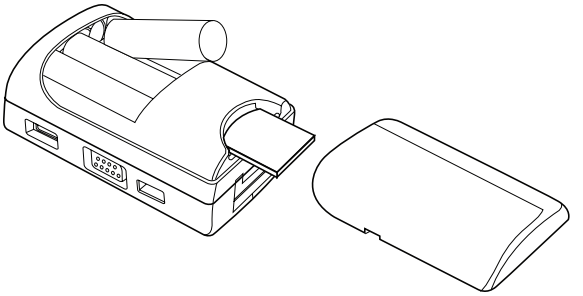
1. Remove the back cover.



WARNING:
Use caution when removing damaged batteries and avoid exposing skin to any battery leakage.

Alice*PDx* back cover removed

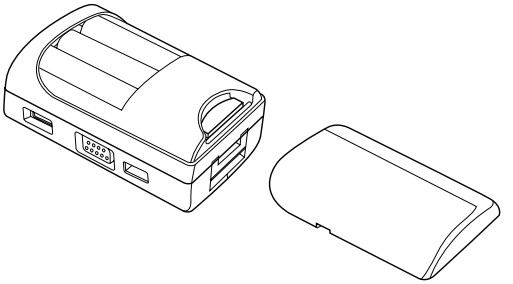
2. Remove used batteries and, if necessary, dispose of in accordance with local regulations.
3. Insert the batteries so that their positive (+) ends match those shown in the diagram in the bottom of the battery chamber.
4. Insert the metal-connector edge of an SD memory card into the card slot. The SD card label should be facing up. Push the card in gently until it clicks into position.



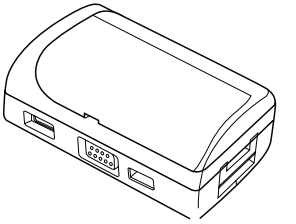
Note: *If the card does not click into position or you feel resistance, it may be upside down. Turn the card over and try again.*

Battery and memory card installation

5. Replace battery cover.



Batteries and SD memory card in place



Replaced Battery Cover

Connecting an Alice*PDx* Device to a Computer

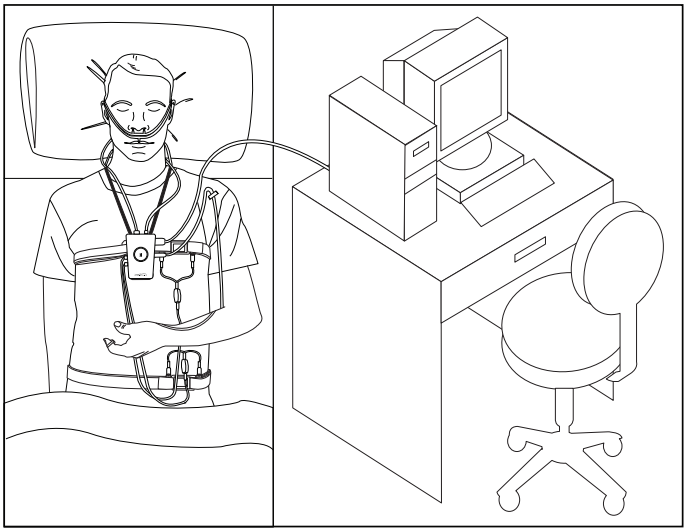
The **Alice***PDx* device can be connected to a computer using the serial-to-USB communication cable. The serial end connects to the **Alice***PDx* device and the USB end connects to your computer. This connection is used to transfer recorded sleep study data in real time to the computer and to configure the **Alice***PDx* device using Sleepware. Because the computer uses the same connection port as a therapy device, the computer must be disconnected if a therapy device is to be connected.

Note: *Data is still recorded on the SD card while the device is connected to a computer.*

Note: *When the cable is connected, your computer may display a note referring to the cable as MobileLink.*

WARNING

Ensure that any computer connected to the **Alice***PDx complies with the safety standard IEC 60950. Only connect the* **Alice***PDx to an IEC 60950 compliant computer when configuring the device or when viewing a sleep study in real time, carefully following the respective instructions. Do not connect the* **Alice***PDx to any other USB compatible device.*



Connecting an Alice*PDx* to a computer

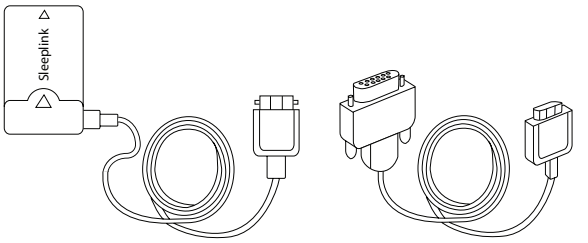
Connecting an Alice*PDx* Device to a Respironics Therapy Device

The **Alice***PDx* device can be connected to a therapy device with a therapy device communication cable. The color coded end of the cable connects to the **Alice***PDx* device and the SleepLink or serial end connects to the therapy device.

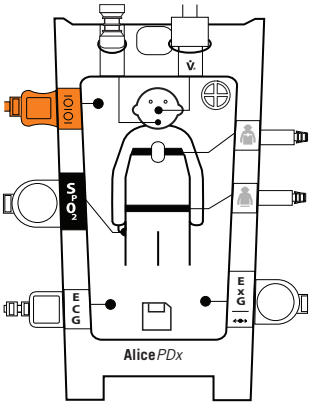
Note: *Refer to the Sleepware manual for a full listing of the available therapy or ventilation parameters that may be recorded.*

WARNING:

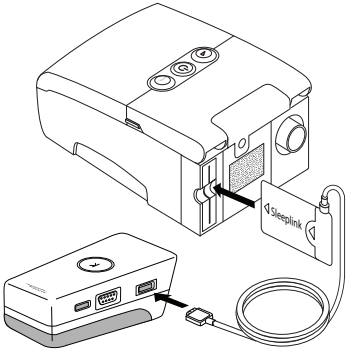
Connecting the **Alice***PDx to a device that is not approved by Respironics with the therapy and/or SleepLink communication cables, may result in a shock hazard to patient. Only devices that are IEC 60601-1 approved may be attached to the* **Alice***PDx.*



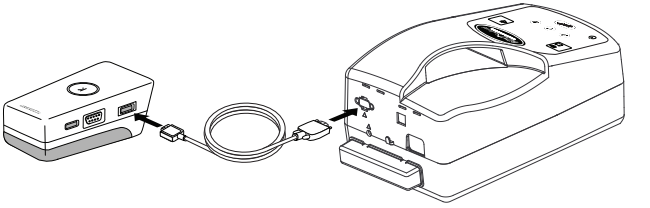
Cable selection



Cable connected to the Alice*PDx*



Alice*PDx* **connecting to a therapy device with a SleepLink card**

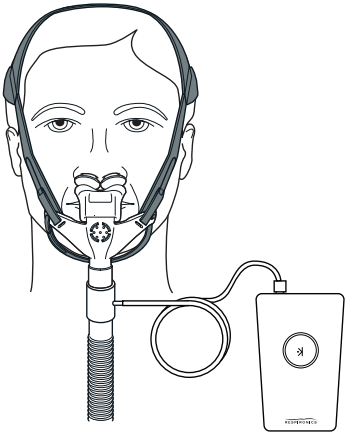


Alice*PDx* **connecting to the Synchrony with a serial cable**

Once connected to the therapy device, the **Alice***PDx* will record data from the device during the sleep study. Depending on the type of therapy device, the **Alice***PDx* will record some or all of the following channels: leak, tidal volume, pressure, flow, and event flags. This data is provided to allow you to determine the therapeutic benefit of the prescribed therapy device.

Connecting to a Non-Respironics Therapy Device

When the **Alice***PDx* is connected to therapy devices not manufactured by Respironics, the data from that device cannot be assured. The **Alice***PDx* will record the pressure and flow from a non-Respironics therapy device, but hand scoring of the other data must be performed to ensure a correct diagnosis. The **Alice***PDx* will connect to a non-Respironics therapy device by connecting to the tubing circuit and the nasal cannula connection, as shown in the figure below.



Alice*PDx* **connected to the tubing circuit when using a non-Respironics therapy device**

Connecting an SD Card Reader to a Computer

Any Windows-capable, "plug-and-play" SD card reader can be used to read and transfer data from an SD card to your computer. After recording, remove the SD card from the **Alice***PDx* and place into a connected reader.

4. Preparing for a Sleep Study Acquisition

This chapter describes how to configure the **Alice***PDx* device for use with a patient and how to prepare a patient for a sleep study. This chapter also explains how to start and stop an acquisition. See *Appendix C*, *Understanding Channels*, for information on the channels that can be recorded, and see Sleepware's online help for detailed instructions on using the Sleepware software.

Overview

There are three operational scenarios for which the **Alice***PDx* device may be used.

Scenario 1: Home setting, no auto-start.

Clinicians and patients perform the following process:

- Clinician prepares the **Alice***PDx* device with fresh batteries and SD memory card.
- Clinician connects the **Alice***PDx* device to a computer and configures the **Alice***PDx* device using Sleepware.
- Clinician disconnects the **Alice***PDx* device from the computer.
- Clinician reviews the operation of the **Alice***PDx* and application of all of the sensors with the patient, then sends the device home with the patient. Respironics recommends that the review includes the importance of noting the Good Study Indicator (if configured) at the conclusion of each night's study.
- Patient connects sensors to the device using the color-coded cables and input labels according to the instructions supplied by the clinician.

  The device can be on or off as the cables are connected. If the patient turns on the device prior to connecting sensors, visual indicators flash to show the required connections.
- Patient applies the sensors to his/her body as instructed. The visual indicators stop flashing as connections are made if device is on.
- Patient confirms the device is on and no indicators are flashing, then goes to sleep.

- At the end of the sleep period, the patient should note the status of the Good Study Indicator (if configured) prior to turning off the device.
- Patient turns off the device and returns it to the clinician.
- Clinician transfers the recorded sleep study acquisition from the memory card to a computer and analyzes the acquisition using Sleepware.

Scenario 2: Home setting with auto-start.

Clinicians and patients perform the following process:

- Clinician prepares the **Alice***PDx* device with fresh batteries and SD memory card.
- Clinician connects the **Alice***PDx* device to a computer and configures the **Alice***PDx* device using Sleepware. The configuration includes a specific date and time at which the **Alice***PDx* device will auto-start and begin recording. The clinician may also set the preferred number of consecutive days for the **Alice***PDx* to auto start and stop, to allow for multiple days of recording. For information on how to configure the **Alice***PDx* and set days and times, see the Sleepware manual or online help.
- Clinician disconnects the **Alice***PDx* device from the computer.
- Clinician reviews the operation of the **Alice***PDx* and application of all of the sensors with the patient, then sends the device home with the patient. Respironics recommends that the review includes the importance of noting the Good Study Indicator (if configured) at the conclusion of each night's study.
- Patient connects sensors to the device using the color-coded cables and input labels according to the instructions supplied by the clinician.

  The device can be on or off as the cables are connected. If the patient turns on the device prior to connecting sensors, visual indicators flash to show the required connections.

  Note: *Turning the device on before the auto-start time will override the auto-start if the auto-start time occurs while the device is on. Turning the device off before the set auto-stop time will override the auto-stop.*
- If a therapy device will be used, the patient connects the device to the **Alice***PDx* following the instructions provided by the clinician.
- Patient applies the sensors to his/her body as instructed. If the device is on, the visual indicators stop flashing as connections are made, and the patient turns the device off before the auto-start time.
- The **Alice***PDx* device automatically turns on at the pre-set time.
- Patient confirms that no visual indicators are flashing (meaning all sensor cables are properly connected to the device) and recording begins.

- At the end of the sleep period, the **Alice***PDx* device automatically turns off. The patient should note the status of the Good Study Indicator (if configured) prior to the device turning off.
- Patient returns the **Alice***PDx* device to the clinician.
- Clinician transfers the recorded sleep study acquisition from the memory card to a computer and analyzes the acquisition using Sleepware.

Scenario 3: Attended or Semi-Attended study.

Clinicians perform the following process:

- Prepare the **Alice***PDx* device with fresh batteries and SD memory card.
- Connect the sensors to the patient.
- Connect the **Alice***PDx* device to a computer and configure the **Alice***PDx* device using Sleepware.
- Start the acquisition from the computer using Sleepware.
- Observe the acquisition channels using the Sleepware real-time display and the visual indicators on the **Alice***PDx* device screen to verify the proper connections were made.

  A therapy device can be connected to the **Alice***PDx* device at any time during the sleep period, and the **Alice***PDx* will record data from the therapy device. However, the therapy device uses the same connection port as does the computer. Therefore, the computer must be disconnected if a therapy device is to be connected.
- If the computer is still connected at the end of the sleep period, Sleepware can stop the acquisition, which also turns off the **Alice***PDx* device. Alternatively, the device can be turned off using the power button.
- The recorded sleep study acquisition is transferred from the memory card to the computer by using an SD card reader.
- Once transferred, the acquisition data is analyzed using Sleepware.

The following sections describe, in detail, how a sleep study is conducted with the **Alice***PDx* device using all available channels in an attended (clinical) setting (Scenario 3 above). The clinician may also reference this section when instructing a patient in the application of sensors in scenarios 1 and 2. See *Appendix C, Understanding Channels*, for information about the channels that the **Alice***PDx* equipment supports.

Patient Setup (Attaching Sensors)

Complete the following steps to set up your **Alice***PDx* device and attach sensors to a patient.

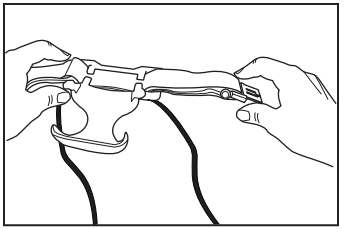
Attaching Basic Set of Sensors

Begin by attaching the chest and abdomen effort belt sensors:

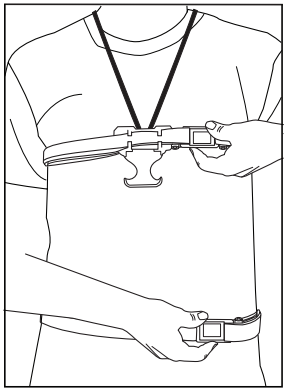
1. Slide the chest effort belt through the slots in the device holster , going from the front of the holster towards the back. (See figure at right.)
2. Connect the neck lanyard by gently pushing the lanyard into the eyelet holes on the holster.
3. Place the lanyard over the patient's head. Then, adjust the lanyard and chest belt so that the holster is in the center of the chest over the patient's sternum, and the belt is evenly aligned with both nipples. (See bottom figure) After the lanyard and holster are in place, the patient's hands are free to apply other sensors.
4. Place the abdominal belt around the patient's stomach so that the plastic part of the belt is directly over the navel and does not rotate around the torso. The fasteners on the belt should be aligned with the hips.
5. Attach the **Alice***PDx* device to the holster so that the gray battery cover is facing toward the patient and the unit opens down and away from the patient's body. The device is opened by sliding the closure latch (found on top of the unit) to the side.

   Note: *If the* **Alice***PDx does not snap into place, the holster may not be attached to the effort belt correctly. When not properly attached, the device may move out of position.*

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

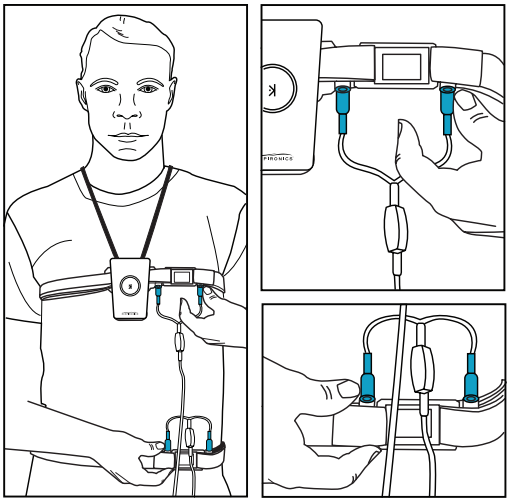


Alice*PDx* **holster fitting on chest belt**



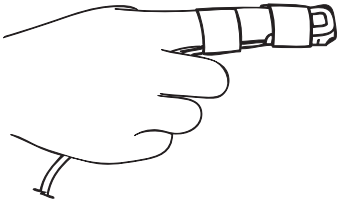
Placement of effort belts

6. Connect the effort belt cables to the effort belts and to the **Alice***PDx* device. Be certain the chest belt connects to the chest connection ( ) and that the abdominal belt connects to the abdominal connection ( ). (See figure below.)

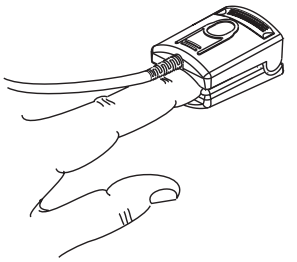


Connecting effort cables to belts and Alice*PDx*

7. Attach the finger SpO_2 ( ) connector to the patient's forefinger and connect the other end to the **Alice***PDx* device. If the SpO_2 sensor is too short, use the SpO_2 extension cable. The SpO_2 sensor measures the oxygen saturation level in the blood.



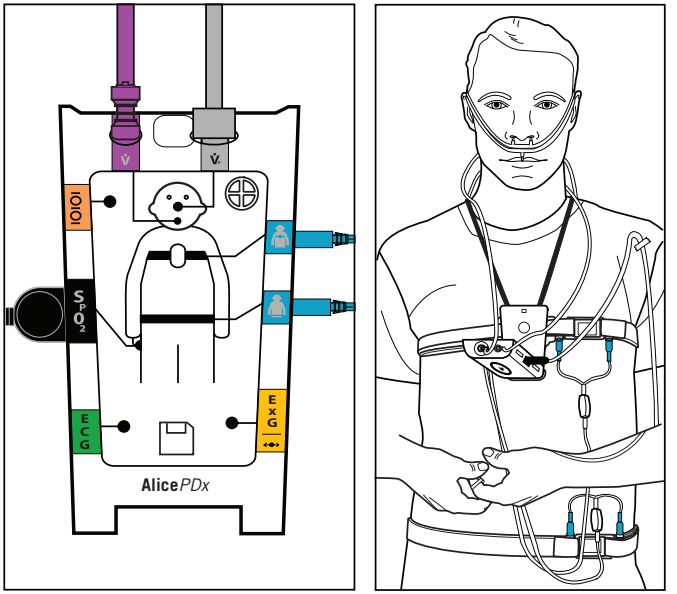
Wrap style SpO_2 sensor



Clip style SpO_2 sensor

8. Connect the nasal cannula ( ) and oral thermistor ( ) to the device and position the sensors on the patient's face.

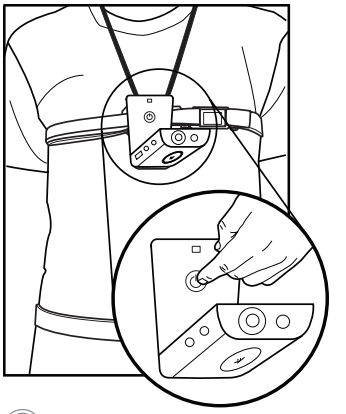
The figure below shows all of the basic connections.



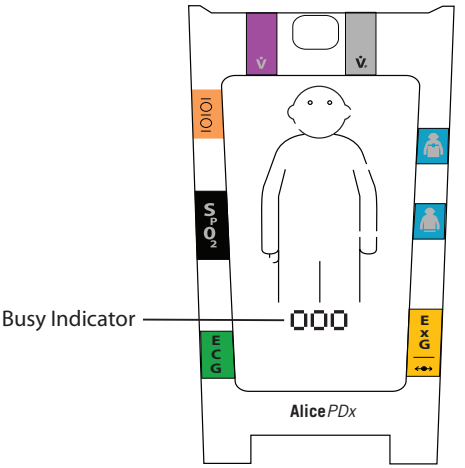
Effort belts, SpO_2 sensor, cannula, and thermistor connected

9. Turn on the **Alice***PDx* device, if it's not already on.

   When the display appears, all of the icons on the display are shown for several seconds. Then, all of the icons are cleared and the busy indicator appears on the screen until the device is initialized.

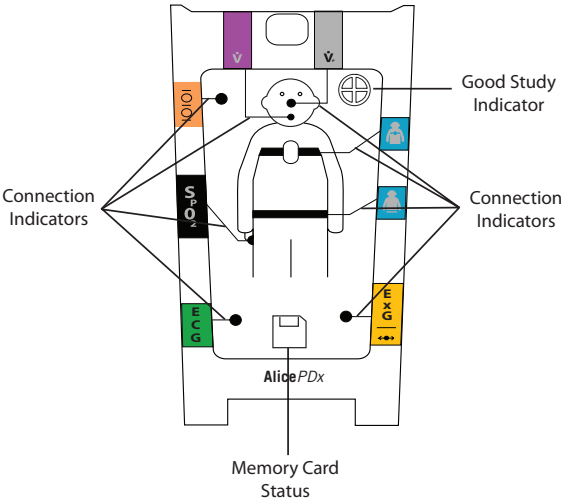


Alice*PDx* power button



Initialization screen

Once initialized, several symbols appear on the screen: Good Study indicator, memory card status, and the connection indicators. If a connection is loose or missing, the indicator symbol for it flashes until the connection is made.



Display screen

Note: *If at any time a connector becomes detached, the corresponding indicator flashes until the connector is reattached. The light near the open/close latch on the device also flashes until the connection has been restored or if 10 minutes pass with no action being taken. All indicators should be solid in order to accurately record signals.*

Note: *The SpO_2 can take up to 30-40 seconds to acquire a "good" signal.*

At this point, the device could be closed, and the patient allowed to sleep.

To conduct a more thorough study, additional optional sensors (e.g., ECG, EEG/EOG/EMG) may be attached to the patient and connected to the **Alice***PDx* device.

Attaching Optional ECG Electrodes

The **Alice***PDx* device supports a single lead, a 6-lead, or a 7-lead ECG. The single lead ECG uses two or three cables (the right leg is optional, depending on whether an EEG Neuroground is also used with the patient). The 6-lead ECG uses three or four cables (right leg optional), and the **Alice***PDx* calculates the six channels by cross-referencing the signals. The 7-lead ECG uses three or four cables, including an intercostal chest lead, which can be placed at any of the V positions (V1-V6), and the **Alice***PDx* calculates the seven channels by cross-referencing the signals.

Type	Lead Number	Colors
North American ECG yoke (according to AAMI, AHA-Code, or US Code)		
Single Lead ECG	Lead II	RA (right arm) = White LL (left leg) = Red RL (right leg) = Green **Note:** *Do not connect the RL lead if you are using an EEG Neuroground.*
6-Lead ECG	Lead I	RA (right arm) = White LA (left arm) = Black RL (right leg) = Green **Note:** *Do not connect the RL lead if you are using an EEG Neuroground.*
	Lead II	RA (right arm) = White LL (left leg) = Red
7-Lead ECG	Lead I	RA (right arm) = White LL (left leg) = Red RL (right leg) = Green **Note:** *Do not connect the RL lead if you are using an EEG Neuroground.*
	Lead II	RA (right arm) = White LL (left leg) = Red V (chest) = Brown

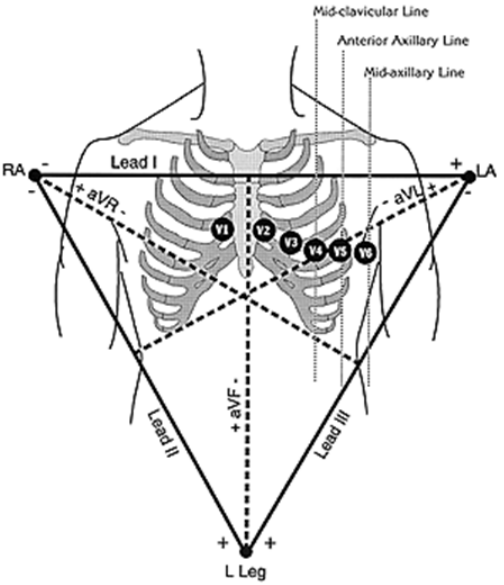
Follow your facility's approved procedure for attaching the ECG electrodes to the patient.

If your facility does not have a standardized procedure, below are suggested instructions.

1. Snap the ECG leads onto adhesive electrode patches.
2. Attach the patch for the right arm to the top right side of the patient's chest, approximately one inch (2.54 cm) below the collarbone.
3. Attach the patch for the left arm to the top left side of the patient's chest, approximately one inch (2.54 cm) below the collarbone. The green lead is for the ECG Ground. This completes the procedure for a single-lead ECG. If you want to complete a 5-lead ECG, continue with Step 4.
4. Attach the patch for the right leg on the patient's right side at the lowest rib. Do not place the patch forward toward the patient's stomach; it should be placed directly on the patient's side.

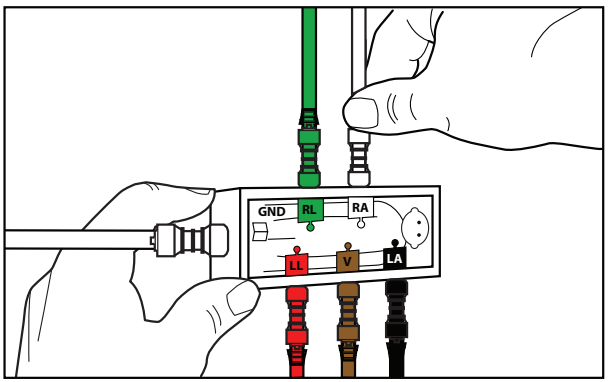
5. Attach the patch for the left leg on the patient's left side at the lowest rib. Do not place the patch forward toward the patient's stomach; it should be placed directly on the patient's side.

6. Attach the patch for the ECG V to the chest using any of the "V" positions as seen in the figure below.



Placements of ECG V

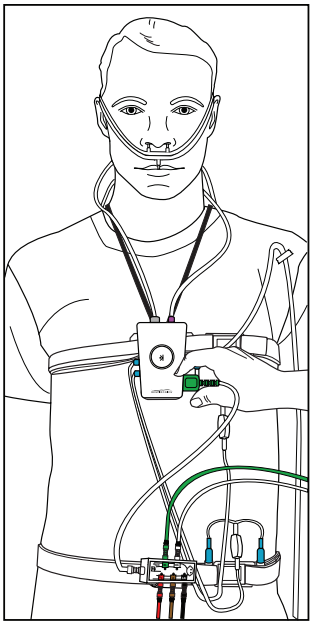
7. Connect the ECG lead cables to appropriate color-coded locations on the ECG yoke, as shown in the figure below.



8. Attach the ECG yoke to the chest effort belt and connect yoke cable to the **Alice***PDx* device, as shown in the figure at right.

CAUTION

If you use an ExG Neuroground, do not use the right leg/ground ECG lead.



ECG yoke attached to chest belt and Alice*PDx* Device

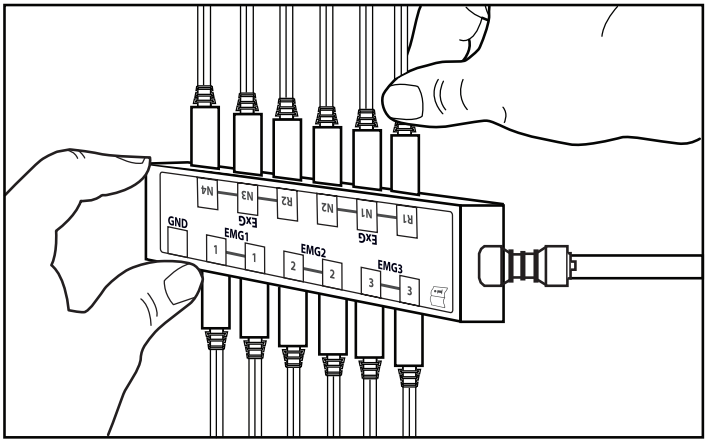
Attaching ECG lead cables to the ECG yoke

Attaching Optional ExG Electrodes

Attach the ExG electrodes in the manner specified by your facility's protocol and based on the configuration you choose.

Complete the following steps to attach ExG sensors to a patient:

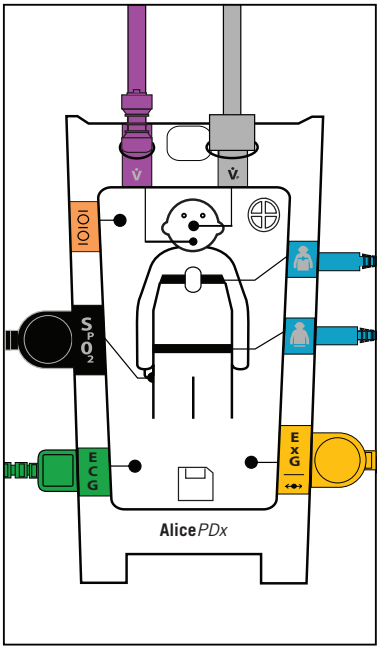
1. Following the manufacturer's recommendations, attach the ExG leads to the patient's scalp in accordance with your facility's procedures.
2. The **Alice***PDx* ExG inputs are arranged as follows:
    - R1 – reference electrode
        - o N1 – electrode input tied to reference R1
        - o N2 – electrode input tied to reference R1
    - R2 – reference electrode
        - o N3 – electrode input tied to reference R2
        - o N4 – electrode input tied to reference R2
    - The two reference inputs (R1 and R2) are provided and would typically be used for the electrodes placed on the A1/M1 and A2/M2 reference locations on the head. The N1 and N2 inputs use R1and only R1 as their reference. Likewise, the N3 and N4 inputs use R2 and only R2 as their reference. The N1, N2, N3, and N4 electrodes can be used for EEG or EOG leads.
    - The mapping of these inputs to specific electrode points on the head is part of the configuration process that is performed by the Sleepware software. The placement of electrodes needs to be consistent with the current **Alice***PDx* configuration. Attach the electrodes to the head and plug them into the appropriate input on the ExG yoke.
    - The determination of whether the setup uses an ipsilateral or contralateral orientation is determined during the **Alice***PDx* configuration process. In the U.S., adult studies use a contralateral setup. In Europe, an ipsilateral setup is used.
3. Plug the ExG connector into the **Alice***PDx* device.
4. Place the Neuroground electrode on the center of the patient's forehead, and plug the lead into the Neuroground input on the ExG yoke.
5. Connect the ExG (EEG/EOG/EMG) lead cables to the ExG yoke, as shown in the figure on the next page.

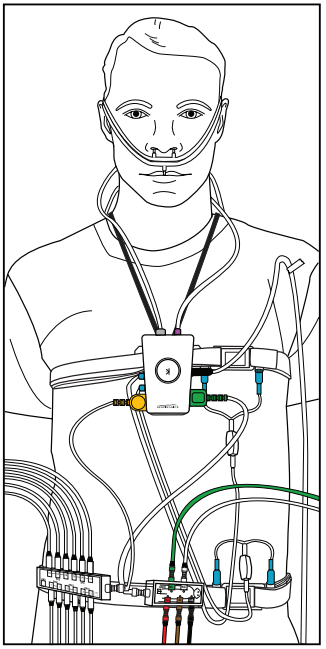


CAUTION
If you use an EEG Neuroground, do not use the right leg/ground ECG lead.

Attaching ExG cables to ExG yoke

6. Attach the ExG yoke to the other side of the chest effort belt and connect the yoke cable to the **Alice***PDx* device.
7. With all of the sensors and cables connected, close the **Alice***PDx* device cover and turn on the **Alice***PDx*, if it is not on already, to begin the sleep study.





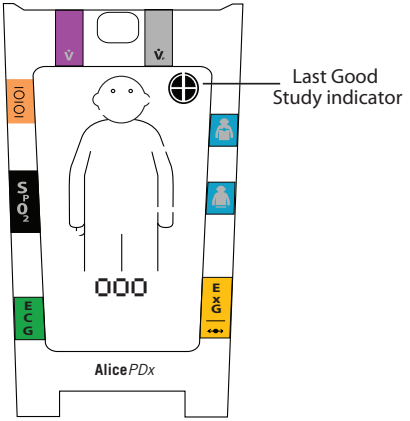
Alice*PDx* **with all connections made**

Pre-Acquisition Equipment Checks

Before running an acquisition, you should review your cable connections and check your equipment as specified below:

1. Verify that the **Alice***PDx* device is on and that the error indication symbol () is not visible. Normally, the error indicator is not visible. If it is visible and flashing, turn off the device and contact Respironics.
2. Verify that all the visual indicators for the configured channels located on both sides of the screen on the **Alice***PDx* device are solid (not flashing).
3. Check the battery indicator symbol (). Normally, the battery indicator does not remain on the screen. However, if the battery is low, the battery indicator does appear and flashes until it is replaced.
4. Check the memory card symbol () to verify that a memory card is inserted and there is sufficient memory available on the memory card to store the results of the sleep study. If the card is nearly full, it flashes until it is replaced. When the card is completely full, recording stops. Once a new memory card is inserted, the device must be turned off and then on again before the new card will be recognized.
5. If the **Alice***PDx* has been configured to show the Good Study symbol (), check the Good Study symbol to verify that it is ready to begin. (An empty circle indicates that a sleep study has not begun or the device has gathered less than 25% good quality data.)
6. Patient goes to sleep.

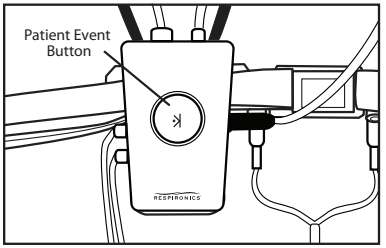
As the study progresses, the Good Study symbol displays the status of the good quality data gathered for the study in 25% increments. The patient should note the Good Study Indicator at the conclusion of each night's study. The last Good Study indicator to appear on the screen before the device is turned off will reappear on the screen once the device is turned back on. This last Good Study indicator will appear on the screen during warm up. Once the device remains on for ten minutes, this last study indicator will no longer appear. This feature enables you to learn how much of the sleep study was successful in the event that the patient forgets to check the Good Study indicator.



Last Good Study indicator on screen

Recording Patient Events

A patient can record an event during the acquisition by pressing the Patient Events button on the **Alice***PDx* device to indicate a non-sleep event. For example, if the patient wakes up and gets out of bed during the night, he or she could make a note of it by pressing the Patient Event button, located on the front of the closed device.



Patient Event button

5. Performing an Acquisition

This chapter discusses how to begin acquisitions, view them in real time, and how to import acquisition data from an SD memory card.

Starting a Real Time Acquisition

To start the data acquisition, complete the following steps:

1. If Sleepware's Alice Starter module is not already running on your computer, double-click on the **Alice Starter** icon ().

   The name of your **Alice***PDx* device appears in the Starter bar at the top of the computer screen, along with the words "No Signal." This indicates the **Alice***PDx* device is not connected.

2. Connect the **Alice***PDx* device to the computer with the serial to USB communication cable. If the device is on and recording when it is connected, the **Alice***PDx* button on the Sleepware starter bar appears in green and displays "Recording." If the **Alice***PDx* device is off at the time it is connected, and then turned on after the connection is made, the **Alice***PDx* button on the starter bar appears in blue and displays "Idle."

3. Left-click on the name of the **Alice***PDx* device in the Starter bar.

   If the **Alice***PDx* device is currently recording, the online view window appears and displays waveforms in real time.

   If the **Alice***PDx* device is not recording and is "Idle," the Start Acquisition window is displayed. This window displays the current patient data and configuration for the connected **Alice***PDx* device.

4. If the Start Acquisition window is displayed, edit the patient data accordingly, or select a new configuration if desired. Then, select the **Start Acquisition** button in the window. The **Alice***PDx* device starts recording. The online view window appears and displays waveforms in real time.

As the acquisition progresses, the Good Study symbols (if configured) display the status of good quality data gathered for the study in 25% increments. (Refer to *Symbol and Label Definitions* for details.) The patient should note the Good Study Indicator at the conclusion of each night's study. The last Good Study indicator to appear on the screen before the device is turned off will reappear on the screen once the device is turned back on. This feature enables you to learn how much of the sleep study was successful in the event that the patient forgets to check the Good Study indicator. Refer to Sleepware's online help for additional information on viewing and scoring acquisitions obtained from the **Alice***PDx* device.

Stopping a Real-Time Acquisition

To stop a real-time acquisition, click the **Stop** button on the online view window in Sleepware, or power off the **Alice***PDx* device directly.

Importing Acquisition Data from an SD Memory Card

Acquisition data is always stored on the SD card in the **Alice***PDx* device, even when the acquisition is being viewed in real-time.

To import data from an SD card using Sleepware:

1. Remove the back cover from the **Alice***PDx* device.
2. Depress and release the SD card. The card will pop-out slightly so that you can grip it.
3. Remove the SD card and place it in the SD card reader connected to your computer.
4. From Sleepware, right-click on the **Alice***PDx* device button on the Starter bar and select **Import SD Card**.

   The Import Acquisitions from SD Card window is displayed.
5. Click the **Browse** button and navigate to the appropriate file folder to store the acquisition data on your computer.
6. Click the **Import** button to download the acquisition data.

   Note: *You can erase the data on the SD card after downloading by clicking on the **Clear SD Card After Import** option.*

6. Cleaning and Maintenance

This chapter describes how to clean the **Alice***PDx* device and sensors.

Alice*PDx* Device and Holster

Clean the **Alice***PDx* between uses with patients.

To clean the **Alice***PDx* device and holster:

- Moisten a soft cloth with soapy water or a mild detergent. Squeeze the cloth to remove excess water.
- Gently, wipe the cloth over the device. Then, dry with a clean, dry cloth.

CAUTION

Do not autoclave, gas, or pressure sterilize **Alice***PDx equipment.*

CAUTION

Never use harsh cleaning agents or chemicals. Never spray cleaner directly onto the device.

CAUTION

Do not immerse the **Alice***PDx device in any fluids.*

CAUTION

Make sure all parts are thoroughly dry before using.

Carrying Case

Surface clean with a moist cloth. If necessary, use a mild detergent, and then remove the detergent solution with a damp cloth. Do not use bleach. Air dry.

Lanyard

Hand wash in cold water with a mild detergent. Do not use bleach. Hang to dry or tumble dry on low and remove promptly from the dryer.

Sensors

When the sleep study is finished, you should dispose of sensors, if they are for single patient use, or clean the sensors after removing them from the patient, if they are reusable. Some sensors require special cleaning. Never immerse the sensors in liquid.

Follow these general guidelines when cleaning the sensors:

- Unplug all sensors and cables from the **Alice***PDx* device before cleaning.
- Follow the manufacturer's instructions for cleaning and disinfecting any monitoring and detecting equipment used with the **Alice***PDx* device.

Note: *Equipment or sensors purchased from other manufacturers may require different methods of cleaning and disinfecting.*

ExG

Clean the ExG electrodes following the procedures used by your facility and in accordance with the electrode manufacturer's guidelines.

To clean the ExG yoke, follow the cleaning instructions for the **Alice***PDx* device.

ECG

After one use, dispose of the stick-on ECG electrode patches. Clean the ECG electrodes following the procedures used by your facility and in accordance with the electrode manufacturer's guidelines.

To clean the ECG yoke, follow the cleaning instructions for the **Alice***PDx* device.

Note: *Follow the manufacturer's guidelines for cleaning sensors for any auxiliary devices used with the* **Alice***PDx device.*

Cannula and Thermistor Sensors

After one use, dispose of the cannula.

If using a thermistor airflow sensor, clean the sensor and the sensor cable following the procedures used by your facility and in accordance with the electrode manufacturer's guidelines.

Effort Belts

Clean the effort sensors and belts following the procedures used by your facility and in accordance with the electrode manufacturer's guidelines.

Maintenance

There are no user serviceable components in the **Alice***PDx*. Other than routine cleaning, there is no additional user maintenance or calibration required. Any device, channel, or signal failures should be referred to a Respironics Service facility.

WARNING
Periodically inspect the sensor cables for damage or signs of wear. Discontinue use and replace if damaged.

7. Troubleshooting

This chapter describes problems you may experience with your **Alice***PDx* device and provides possible solutions.

Problem	Solution
Low SpO_2 values	• Check and adjust sensor placement, if necessary • Try another sensor • Assess patient
Sensor indicators flashing (other than SpO_2 or nasal cannula)	• Check sensor connections from the patient to the device • Try another sensor
SpO_2 connection () flashing	• Check if the probe may have come loose or fallen off
Nasal cannula connection () flashing	• Check if cannula is inserted properly • Check placement on patient
Display is blank	• Try new batteries • Possible device failure, contact Respironics Product Support for assistance
Wrench () flashing on screen	• Device error, contact Respironics Product Support for assistance

If your problem is still not resolved after following the solutions described above, contact Respironics Product Support for further assistance at 1-800-345-6443.

8. Specifications

Alice*PDx* **Device**

Size

Dimensions: 5″ L x 3″ W x 2″ H (12.7 cm x 7.62 cm x 5.08 cm)

Weight: Approximately 8 oz (230 grams), (weight does not include batteries)

Classifications and Standards Compliance

Classifications

The **Alice***PDx* device is classified as follows:

- Type of Protection Against Electric Shock: Internally powered equipment.
- Degree of Protection Against Electric Shock: Type BF Applied part
- Degree of protection against harmful ingress of water:
  - IPX0 (Ordinary protection against the ingress of liquids)
- Mode of Operation: Continuous operation
- Not suitable for use in the presence of a flammable anaesthetic mixture with air, oxygen, or nitrous oxide

Standards Compliance

The **Alice***PDx* device is designed to conform to the following standards: IEC 60601-1, IEC 60601-1-2, EN 60601-1, EN 60601-1-2, UL 60601-1, CSA 22.2 No. 601.1, and AS 3200.1.0.

Power Requirements

Three AA (1.5V) alkaline batteries, 0.43 watts (typ).

Alice*PDx* Temperature and Storage Information

	Operation	Storage
Temperature:	41°F to 95°F (+5°C to +35°C)	-4°F to 140°F (-20°C to +60°C)
Humidity:	15% to 95% RH non-condensing	15% to 95% RH non-condensing
Atmospheric Pressure:	70 to 102 kPa	70 to 102 kPa

SpO_2 Sensors

Oxygen Saturation Range	0 to 100%	
Pulse Rate Range	18 to 300 pulses per minute	
Measurement Wavelengths Using Nonin Sensors	Red: 660 nanometers @3mW Nominal Infrared: 910 nanometers @ 3mW Nominal	
Accuracy SpO_2 (70-100%)(± 1 SD)	No Motion	
	- Adults, Pediatrics	± 2 digits
	- Neonates	± 3 digits
	Motion	
	- Adults, Pediatrics	± 2 digits
	- Neonates	± 3 digits
	Low Perfusion	
	- Adults, Pediatrics	± 2 digits
	- Neonates	± 3 digits

Standard Deviation is a statistical measure: up to 32% of the readings may fall outside these limits.

Heart Rate	No Motion (18 - 300 BPM)	
	- Adults, Pediatrics, Neonates	± 3 digits
	Motion (40 - 240 BPM)	
	- Adults, Pediatrics, Neonates	± 5 digits
	Low Perfusion (40 -240 BPM)	
	- Adults, Pediatrics, Neonates	± 3 digits

Disposal

Dispose of the system components in accordance with local regulations.

Appendix A: Glossary

The following terms and acronyms appear in this manual:

Acquisition	A collection of polysomnographic data that has been acquired during a patient study.
Configuration	The set of channels used to acquire polysomnographic data.
ECG	Electrocardiogram (also called EKG) – A recording of cardiac electrical activity. In sleep testing, this channel is used to assess heart rate and rhythm.
EEG	Electroencephalogram – A recording of electrical brain activity. With the EMG and EOG, the EEG is one of three basic variables used to score wake and sleep and to identify sleep stages. The EEG is the primary variable for sleep staging.
EMG	Electromyelogram – A recording of muscle electrical activity. The chin EMG is measured by surface electrodes, and along with the EEG and EOG, it is one of the three basic variables used to score wake and sleep and to identify sleep stages.
EOG	Electrooculogram – A recording of voltage changes resulting from shifts in position of the eye. Along with the EEG and EMG, the EOG is one of the three basic variables used to score wake and sleep and to identify sleep stages.
ExG	A generic input channel that can be configured as EEG, EOG, or EMG.
LED	Light Emitting Diode.
Montage	A montage (as distinguished from an acquisition configuration) is a way to display re-referenced EEG and EOG data during or after an acquisition. Each acquired EEG channel measures the difference in electrical potential between a given (active) electrode and a reference. The montage tool recombines EEG/EOG data in order to display the difference in potential between any two electrodes.

PC	Personal Computer.
Polysomnography	Recording of multiple channels of physiologic data during sleep.
PSG	Polysomnography.
SD	Secure Digital (flash memory card).
Sleepware	The Respironics software application that runs via the Windows operating system and that receives and analyzes physiologic data from Respironics diagnostic equipment.
Sleepware Starter Bar	The component of Sleepware that appears at the top of the computer screen and is used during equipment setup for configuration and during data acquisitions to view settings.
SpO_2	Arterial oxygen saturation level via pulse oximetry.

Appendix B: EMC Information

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
Radiated RF emissions CISPR 11	Group 1 Class B	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Conducted RF emissions CISPR 11	Not applicable for battery operated devices	The device is suitable for use in all establishments, including domestic establishments.
Harmonic emissions IEC 61000-3-2	Not applicable for battery operated devices	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Not applicable for battery operated devices	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrical Fast Transient/ Burst IEC 61000-4-4	±2 kV for Power Supply Lines ±1 kV for Input-Output Lines	Not applicable for battery operated devices ±1 kV for input/output lines	This device is suitable for use in all establishments, including domestic establishments.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable for battery operated devices	This device is suitable for use in all establishments, including domestic establishments.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Not applicable for battery operated devices	This device is suitable for all establishments, including domestic establishments
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home or hospital environment.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

b: Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and This Device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this device as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Power Output of Transmitter (W)	**Separation Distance According to Frequency of Transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

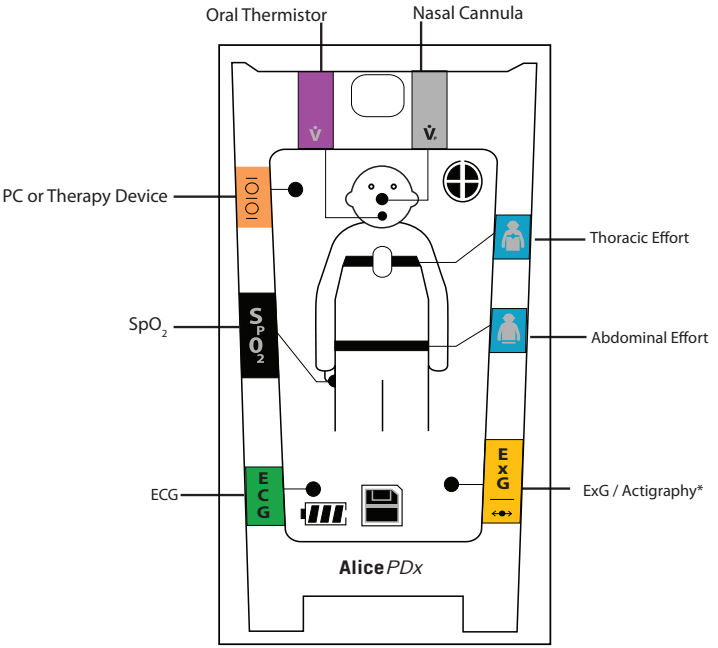
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Appendix C: Understanding Channels

Channels refer to the different types of data collected by the sensors and therapy devices connected to the patient. The set of channels used in any particular sleep study is referred to as a configuration.

You can configure the channels based on the type of information you need to collect for the study. Once you set up the patient and have the data coming in from the channels you configured, you can use Sleepware to filter channels, create a montage, etc. Refer to Sleepware's online help for information on how to build configurations and create montages.

The channels available on the **Alice***PDx* device are shown below.



**Actigraphy reserved for future use.*

Channels available on the Alice*PDx* device

The table below provides the following information about each of the **Alice***PDx* device channels:

- The **Channel** column lists the name of the channel.
- The **Channel Quantity** column tells how many inputs are available on the **Alice***PDx* device for each channel.
- The **Sample Size** (in bits) column specifies the bit resolution for the channel being acquired.
- The **Initial Sampling Frequency** (in Hertz) tells us the initial sampling rate before storage.
- The **Recorded Frequency** (in Hertz) column tells you how often the data is stored per second. Many channels have several frequency rates available.
- The **Range** column specifies the range of values to which the data corresponds.
- The **Units** column specifies the unit of measure for each channel.

Channel	Channel Quantity	Sample Size (bits)	Initial Sampling Frequency (Hz)	Recorded Frequency (Hz)	Range	Units
ECG I	1	10	1000	200	±4	mV
ECG II	1	10	1000	200	±4	mV
ECG II HF	1	10	1000	1000	±4	mV
ECG V	1	10	1000	200	±4	mV
ExG (N1-R1)	1	10	1000	200	±500	mV
ExG (N2-R1)	1	10	1000	200	±500	mV
ExG (N3-R2)	1	10	1000	200	±500	mV
ExG (N4-R2)	1	10	1000	200	±500	mV
ExG (R1-R2)	1	10	1000	200	±500	mV
ExG (EMG1(+)-EMG1(-))	1	10	1000	200	±150	mV
ExG (EMG2(+)-EMG2(-))	1	10	1000	200	±150	mV
ExG (EMG3(+)-EMG3(-))	1	10	1000	200	±150	mV
Thoracic Effort	1	16	100	100	±100	N/A
Abdominal Effort	1	16	100	100	±100	N/A
Thermistor Based Flow	1	16	100	100	±100	N/A
Therapy Pressure	1	12	10	10	-5 - +4.0	cmH_2O
Patient Pressure Based Flow (cannula)	1	16	200	200	±100	cmH_2O
Raw Snore	1	10	500	500	N/A	N/A
Body Position	1	10	100	1	0 - 12	N/A

Channel	Channel Quantity	Sample Size (bits)	Initial Sampling Frequency (Hz)	Recorded Frequency (Hz)	Range	Units
SpO_2	1	N/A	75	3	0 - 100	%
Pulse Rate	1	N/A	N/A	3	0 - 300	BPM
Plethwave	1	N/A	N/A	75	N/A	N/A
Alice*PDx* Event (Patient Button)	1	N/A	N/A	10	N/A	N/A
Respironics Therapy Device RT Channels	8	Refer to therapy device	N/A	10	Refer to therapy device	Refer to therapy device

Each physical input channel is described in more detail below:

Airflow

The airflow channels are used to display data from a device that measures the patient's airflow. You can use the airflow sensor channel type by connecting a Respironics thermistor or pressure cannula airflow sensor to the **Alice***PDx* device.

Note: *If you label this channel "Flow," the Sleepware software can scan the data and automatically score apneas and hypopneas. Refer to Sleepware's online help for more information.*

You can customize parameters for this channel. Refer to the table above for a detailed description of airflow channel features. As you add this channel to your configuration, you can enter your own label (up to eight characters) from the channel details form.

Body Position

The body position channel tells you the orientation of the patient's body in the bed. The position sensor can report five possible positions:

- Supine (patient is sleeping on their back)
- Prone (patient is sleeping on their stomach, facedown)
- Right Side
- Left Side

You can select customized parameters for this channel. Please refer to the table on the previous page for a detailed description of Body Position channel features. As you add this channel to your configuration, you can enter your own label (up to eight characters) from the channel details form.

ECG

The ECG channel type is used to display data from an electrocardiogram channel. To use this channel, connect an ECG electrode to the ECG inputs on the **Alice***PDx* device as needed.

You can set customized parameters for this channel. Please refer to the table above for a detailed description of ECG channel features. As you add

this channel to your configuration, you can enter your own label (up to eight characters) from the channel details form.

ExG

The ExG channel type is used to display data from an electroencephalogram (EEG) channel, electooculogram (EOG) channel, or electromyelogram (EMG) channel.

You can select customized parameters for this channel. Please refer to the table above for a detailed description of ExG channel features.

Effort

Abdominal and Chest (Respiration)

The respiration channel type is used to display chest and abdomen effort signals and transthoracic inductance signals.

The **Alice***PDx* device provides two zRIP effort channels: thoracic effort and abdominal effort. The Alice Sleepware scans all effort channels to detect apneas in combination with the airflow channel.

You can use the effort channel type by connecting the chest and abdominal effort belts to the inputs on the **Alice***PDx* device. As you add this channel to your configuration, you can enter your own label (up to eight characters) from the channel details form.

Snore

The snore channel type is used to display data derived from the pressure based flow cannula that represents a snore waveform.

You can select customized parameters for this channel. Please refer to the table above for a detailed description of snore channel features. As you add this channel to your configuration, you can enter your own label (up to eight characters) from the channel details form.

SpO_2

The SpO_2 channel type is used to display blood oxygen saturation data from the internal oximeter.

You can use the SpO_2 channel type by connecting the oximeter sensor to the oximeter connection on the **Alice***PDx* device. As you add this channel to your configuration, you can enter your own label (up to eight characters) from the channel details form.

Therapy Device

Therapy devices provide some or all of the following channels, depending on the type of device: leak, tidal volume, pressure, flow, and event flags. This data is provided to allow you to determine the therapeutic benefit of the already diagnosed OSA patient. As you add this channel to your configuration, you can enter your own label (up to eight characters) from the channel details form.

Note: *The* **Alice***PDx will record the pressure and flow from a non-Respironics therapy device, but hand scoring of the other data must be performed to ensure a correct diagnosis.*

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