



“磊士” 多重睡眠生理紀錄儀  
“Respironics” Polysomnography System

衛署醫器輸字第 020622 號

使用前請務必詳閱原廠之使用說明書並遵照指示使用。

型號：Alice PDx

- 產品用途：本儀器是個多功能的紀錄儀，收集及儲存生理訊號。紀錄的資料可以被下載，以圖形顯示在電腦螢幕上，可以被臨床 / 住院醫師列印成診斷報告，以利睡眠呼吸障礙或其他生理障礙的診斷。成人可以在家或醫院機構使用本產品。  
本產品不提供警報功能及當做呼吸暫停或心臟自動監視器。

■警告及注意事項：

警告：以下的警告事項可能會對使用者或操作者造成傷害的情形。

- 如果你有心律調節器，請先諮詢你的醫師做檢查。
- 不要將感應器導線插入電源插座，導線接觸電源插座會出現嚴重的觸電危險。
- 不要將本產品連接到任何與U S B相容的設備。
- 氧氣會助燃。當有人抽菸或有無遮蓋火焰出現時，不要使用氧氣。
- 不要在與氧氣或空氣結合的可燃性麻醉劑混合物的場所使用儀器，或是有笑氣存在的情況下。
- 使用前，確認感應器被正確連接。
- 當固定感應器和導線時，小心排放導線，這將可以降低緊勒、不適、或導線脫落的可能。
- 檢查感應器導線是否損傷或磨損。聯絡你的設備提供者以求支援。
- 如果你注意到本儀器性能有任何原因不明的改變、如果本儀器有摔到或不當操作、如果水流進外殼、或如果外殼破損，請停止使用並連絡你的設備提供者以求支援。
- 修復和調整必須只能被製造廠授權的維修人員執行。自行維修可能會引起傷害、使保固無效、或導致昂貴的損傷。
- 當移除損害的電池時請提高警覺，並防止將皮膚曝露在任何的電池漏出物。
- 請依照當地法規回收或再利用電池，不要燒毀。
- 請使用原廠認可的配件。
- 用治療和 / 或 SleepLink 傳遞線連接本產品到原廠未認可的儀器，可能導致觸電危險。

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看護工警告事項

- 在進行心臟電擊前移除所有病患應用元件的導線。本產品及其配件不能免

受心臟電擊器的影響。

- 不要在核磁共振的環境，或鄰近高發射源頭使用本產品。

■注意：以下注意事項可能會對儀器造成損壞的情形。

- 請遵循原廠對本產品及與其搭配使用的設備之所有建議與用法說明。
- 本產品的操作可能在下述環境中有不良影響：
  - 高頻(電療)設備的操作。
  - 電擊器，或短波治療儀。
  - 放射線(例如 X 射線、斷層掃描)。
  - 磁場(例如核磁共振)。
- 來自於布料及墊子的合成纖維也會因靜電引起干擾。接觸本系統前觸摸無生命物體(例如牆壁)通常能防止靜電產生的問題。
- 來自於電視、收音機、飛機場、警察、火警裝置、和救護站的強力發射信號有可能被接收而被誤解成心臟和 / 或呼吸信號。如果你離這些發射源不到一英里，請詢問原廠顧客服務部以幫助你查明你的系統是否將正常運作。
- 不要將液體放在本儀器之上或附近。如果液體被潑灑在設備上，停止使用直到查明本儀器可以被安全的操作。聯絡你的設備提供者以求幫助。
- 不要將本儀器浸在任何液體裡。

## ■規格

全頻道數	多達 21 個包含可供選擇的 ECG 及 ExG 套件
基本頻道	10 個頻道：pressure-based flow(w/snore)和 thermal airflow、zRIP effort(2)、body position、SpO <sub>2</sub> (也稱血氧脈搏和脈搏率)及 patient marker。多達八個來自於原廠醫療儀器的參數也許能獲得，包括壓力、流量、及漏氣。
選擇套件 / 頻道	ECG 套件；7 個頻道：3 個連接的 ECG 提供 3 個測量及 4 個衍生頻道。 ExG 套件；7 個頻道：4 個神經頻道(ECG 或 EOG)及 3 個鑑別 EMG
輸入阻抗	ECG：10MΩ 每個電極 20MΩ 鑑別 EEG：2MΩ 每個電極 4MΩ 鑑別 EMG：2MΩ 每個電極 4MΩ 鑑別
頻寬	ECG：0.318Hz to 81Hz EEG：0.318Hz to 35Hz EMG：9.7Hz to 86Hz
輸入訊號範圍	ECG：+ / - 4mV EEG：+ / - 500uV



	EEG : + / - 150uV
數位解析度	最高可達 16 bits
初步取樣率	最高達 1000 Hz
最大儲存速率	ECG / ExG 200 Hz, 胸腹部動作及熱氣流 100 Hz, 壓力流 200 Hz, 打鼾 500 Hz, 身體姿勢 1 Hz
通訊界面	原廠醫療儀器專用的串列通訊協定 USB PC 導線, SleepLink 及串列通信導線
系統物理規格	
Alice PDx	
體積	5”L x 3”W x 2”H(12.7 cm x 7.62 cm x 5.08 cm)
重量	8 oz(230 grams), (重量不包含電池)
系統功率需求	三顆 AA(1.5V)鹼性電池, 0.43 瓦(標準)

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製造廠名稱：Respironics, Inc.

製造廠地址：1001 Murry Ridge Lane Murrysville, PA 15668, U.S.A.

藥商名稱：亞靖儀器有限公司

藥商地址：台北縣永和市得和路 269 號 2 樓

## AlicePDx User Manual

# 1. Introduction

**AlicePDx** 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 **AlicePDx** device records information for your healthcare provider and stores it on a removable memory card.

### Intended Use

The **AlicePDx** 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 **AlicePDx** 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.

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## Warnings & Cautions

### Warnings

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

- Consult with your physician prior to performing the study if you have a cardiac pacemaker.
- Do not plug sensor cables into electrical outlets. Cable contact with electrical outlets presents a serious shock hazard.
- Do not connect the **Alice PDx** to any USB compatible device.
- 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 that the sensors are connected properly before using.
- 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.
- Inspect the sensor cables for damage or signs of wear. Contact your equipment provider for assistance.
- 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 your equipment provider 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 leaked battery material.
- 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. Only devices that are IEC 60601-1 approved may be attached to the **Alice PDx**.



### Caregiver Warnings

- Remove all patient cables (applied parts) before performing cardiac defibrillation. The **AlicePDx** device and its accessories are not protected against the effect of cardiac defibrillation.
- Do not use the **AlicePDx** device in a Magnetic Resonance Imaging (MRI) environment or in close proximity to a high emissions source.

### Cautions

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

- Follow all of the manufacturer's recommendations and instructions for the **AlicePDx** and all equipment used with the device.
- Operation of the **AlicePDx** 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 **AlicePDx** device. If liquids are spilled on the equipment, discontinue use until it can be determined that the device can be safely operated. Contact your equipment provider for assistance.
- Do not immerse the **AlicePDx** device in any fluids.



### The base Alice PDx system includes

- Alice PDx device
- Alice PDx professional and user guides
- Carrying case
- Patient setup carrying case overlay
- Serial USB Alice PDx to PC communication cable
- USB SD card reader w/extension cable
- 1 GB SD card
- Alice PDx holster (chest holder for device)
- Neck lanyard for Alice PDx holster
- 2 ea. Pro-Tech zRIP effort belts with wireset
- 5-pack starter pack pressure cannulas
- Oral thermal sensor
- Nonin SpO<sub>2</sub> sensor extension cable
- 4 ea. AA batteries (packaged separately)
- Choice of Nonin SpO<sub>2</sub> probe (packaged separately)

### Ordering information

Item No.	Description
1043941	Alice PDx device kit, domestic/US
1043844	Alice PDx device kit, international
1047990	Alice PDx device kit, Japan
Optional components	
1040808	ExG yoke, Alice PDx, domestic
1048415	ExG yoke, Alice PDx, international
1040809	ECG yoke, Alice PDx, domestic
1040810	ECG yoke, Alice PDx, international
1048916	ECG yoke, Alice PDx, Japan
Accessories	
1040807	Alice PDx to MobileLink cable (PC cable)
1040806	Alice PDx to SleepLink cable
1040805	Alice PDx to RS-232 sleep therapy cable
1053280	Alice PDx holster
1053194	Alice PDx holster neck lanyard
P1328-60	Pro-Flow nasal cannula, adult qty. 60
P1343	Pro-Flow nasal-oral cannula, adult qty. 30
P1379	Oral thermistor, Alice PDx
P1388	Nasal-oral thermistor, Alice PDx
P1391	CPAP titration kit (for non-Respironics therapy devices)
P1837	zRIP adult sensor kit (belts and wiresets), Alice PDx
P1806	zRIP effort sensor, adult (24" to 75") / (61 cm to 190 cm)
P1170	zRIP wireset, Alice PDx
1053952	2-pack SD cards (secure digital card, 1GB ea.)
1053948	Alice PDx quick start guide (carry case overlay) 4-pack
936	SpO <sub>2</sub> reuseable sensor, adult finger clip
953	SpO <sub>2</sub> reuseable flex sensor, adult
954A	Adult flex sensor wrap (25-pack)
Training tools	
1055905	Patient instructions video (DVD)
1055918	Clinician interactive tutorial (CD-ROM)

### Basic PC recommendations:

- Windows®-compatible personal computer running Windows Vista Business, Windows XP Professional or 2000 with a CD-RW drive. A DVD drive is recommended if you will be saving audio/video files onto removable storage media.
- Intel® Pentium® 3 processor (500 MHz) or greater, 32-bit (x86) processor (1 GHz) required for Windows Vista computers
- 512 MB system memory, 1 GB or higher for Windows Vista computers

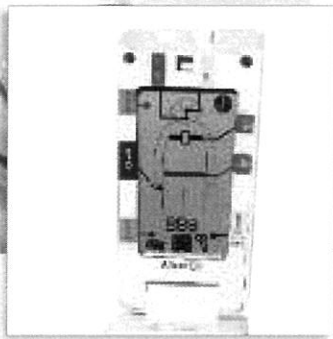
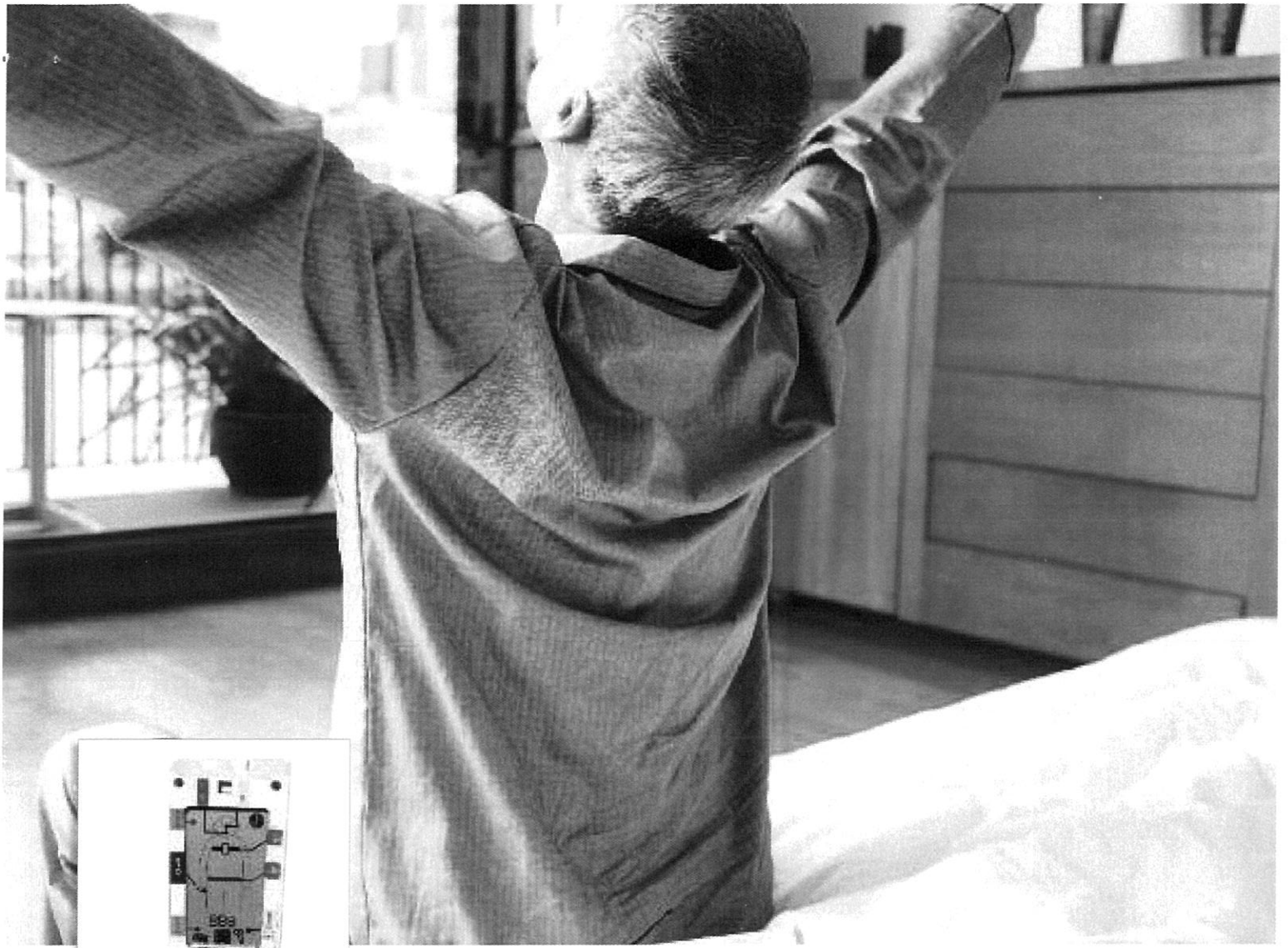
### Specifications

Total channels:	Up to 21 with optional ECG and ExG yokes
Base channels:	10 channels: pressure-based flow (w/snore) and thermal airflow, zRIP effort (2), body position, SpO <sub>2</sub> (also pleth and pulse rate) and patient marker. Up to eight parameters from Respironics therapy devices may be acquired, including pressure, flow and leak.
Optional yokes/ channels:	ECG yoke; 7 channels: 3-lead ECG providing 3 measured and 4 derived channels  ExG yoke; 7 channels: 4 neuro channels (EEG or EOG) and 3 differential EMG, plus references and ground
Input impedance:	ECG: 10MΩ per electrode 20MΩ differential EEG: 2MΩ per electrode 4MΩ differential EMG: 2MΩ per Electrode 4MΩ differential
Bandwidth:	ECG: 0.318Hz to 81Hz EEG: 0.318Hz to 35Hz EMG: 9.7Hz to 86Hz
Input signal range:	ECG: +/- 4mV EEG: +/- 500uV EMG: +/- 150uV
Digital resolution:	Up to 16 bits
Initial sample rate:	Up to 1,000 Hz
Max storage rate:	200 Hz for ECG/ExG, 100 Hz for effort and thermal flow, pressure flow 200 Hz, snore 500 Hz, body position 1 Hz
Communication interfaces:	Serial protocol USB PC cable, SleepLink and serial communication cables for Respironics therapy devices

### System physical characteristics

Alice PDx unit:	
Size:	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)
System power requirements:	Three AA (1.5V) alkaline batteries, 0.43 watts (typical)





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# Good study results, better night's sleep

Alice PDx Diagnostic System



**PHILIPS**

**RESPIRONICS**

sense and simplicity

# Convenient for patients

## Portable testing made easy

The Alice PDx is a portable, diagnostic recording device for Obstructive Sleep Apnea (OSA) screening, follow-up and diagnostic assessment of cardio-respiratory sleep disorders. This flexible and portable sleep system incorporates the advanced features required to meet today's industry needs. It satisfies the portable testing requirements for levels II, III and IV and offers a variety of capabilities, from basic screening to advanced diagnostic evaluation. The Alice PDx enables you to test your patients outside of the lab without compromising study results, helping you to avoid the costs associated with re-testing.

## Flexible

The Alice PDx can be used in a sleep lab, alternative care site or a patient's home. The device is convenient for patients who are uncomfortable with, or have limited access to, a lab facility. It also increases the flexibility that facilities need for in- or out-of-lab services. Rather than having patients in need of sleep testing go untested and lose revenue because of patients who cancel or never show, the Alice PDx provides you with an opportunity to retain patients who meet the criteria for portable testing.

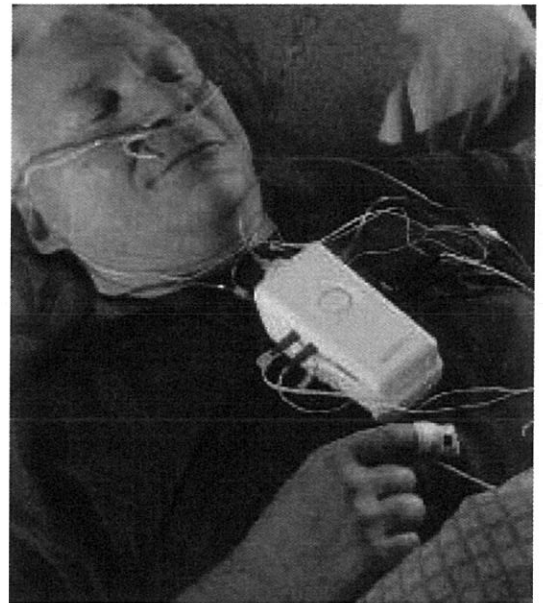
The Alice PDx is field upgradeable, so as new features are added, firmware upgrades will be made available, without having to return your device for service. As updates become available, you will be able to access them via web downloading.

## User friendly

The Alice PDx device interface is easy to use, easy to understand and informative. Color-coded labels, located around the perimeter of the device, indicate where to connect the various sensor leads. The display shows the patient only the sensors that need to be connected. The sensor information and indicators help your patients place the sensors correctly and reduce the need for re-testing due to application errors.

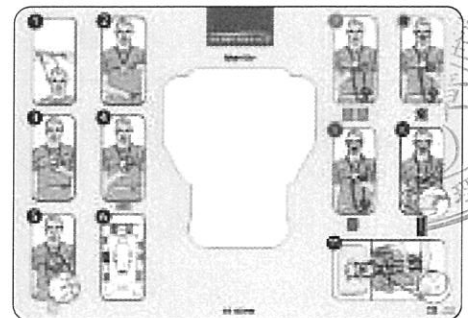
A helpful, color-coded, step-by-step diagram is included with the Alice PDx system to walk patients through the appropriate application process.

The Alice PDx is compact and can accommodate side sleepers. The wires have been specifically designed to minimize excess length to make it easier for patients to manage the wires.



Alice PDx on patient

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Easy reference diagram



Accommodates side sleepers

# Flexible for you

## Good study indicator

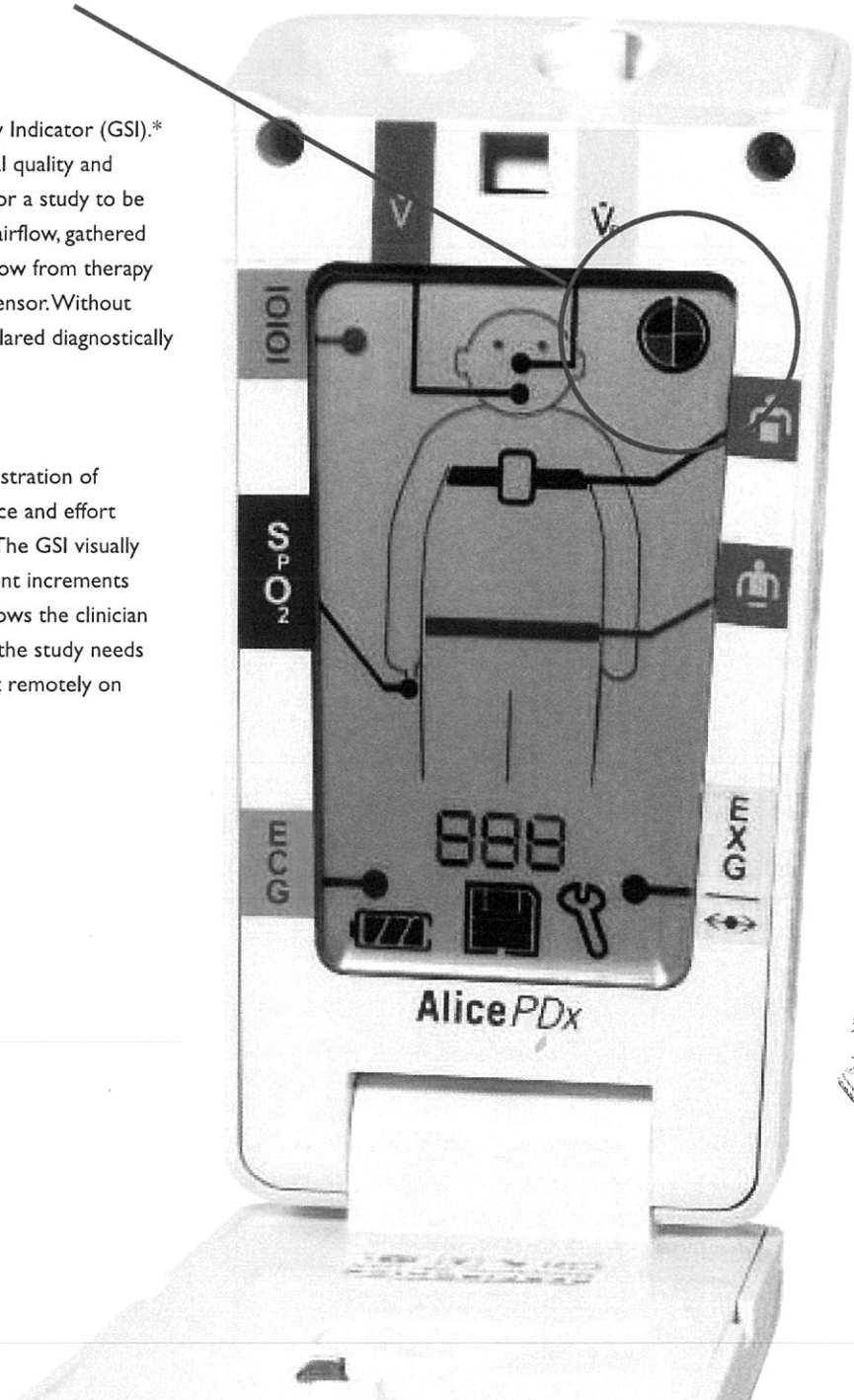
Configurable for the number of hours required for a valid study.

## Minimize re-testing

The Alice PDx incorporates our unique Good Study Indicator (GSI).<sup>\*</sup> The GSI is predicated on airflow and oximeter signal quality and displays the amount of "good quality data" needed for a study to be complete and valid. The indicator measures patient airflow, gathered by the nasal cannula and/or the oral thermistor, airflow from therapy devices, and pulse oximetry, gathered by the SpO<sub>2</sub> sensor. Without either of these signals, the sleep study would be declared diagnostically invalid because of insufficient data.

## Maximize study quality

The Good Study Indicator helps to eliminate the frustration of receiving insufficient study data and the inconvenience and effort involved in rescheduling patients for a repeat study. The GSI visually displays the amount of good quality data in 25-percent increments on the Alice PDx display screen. This information allows the clinician to decide if the patient needs to repeat the study. If the study needs to be repeated, the provider can educate the patient remotely on how to apply the sensors better.



<sup>\*</sup>Patent pending.

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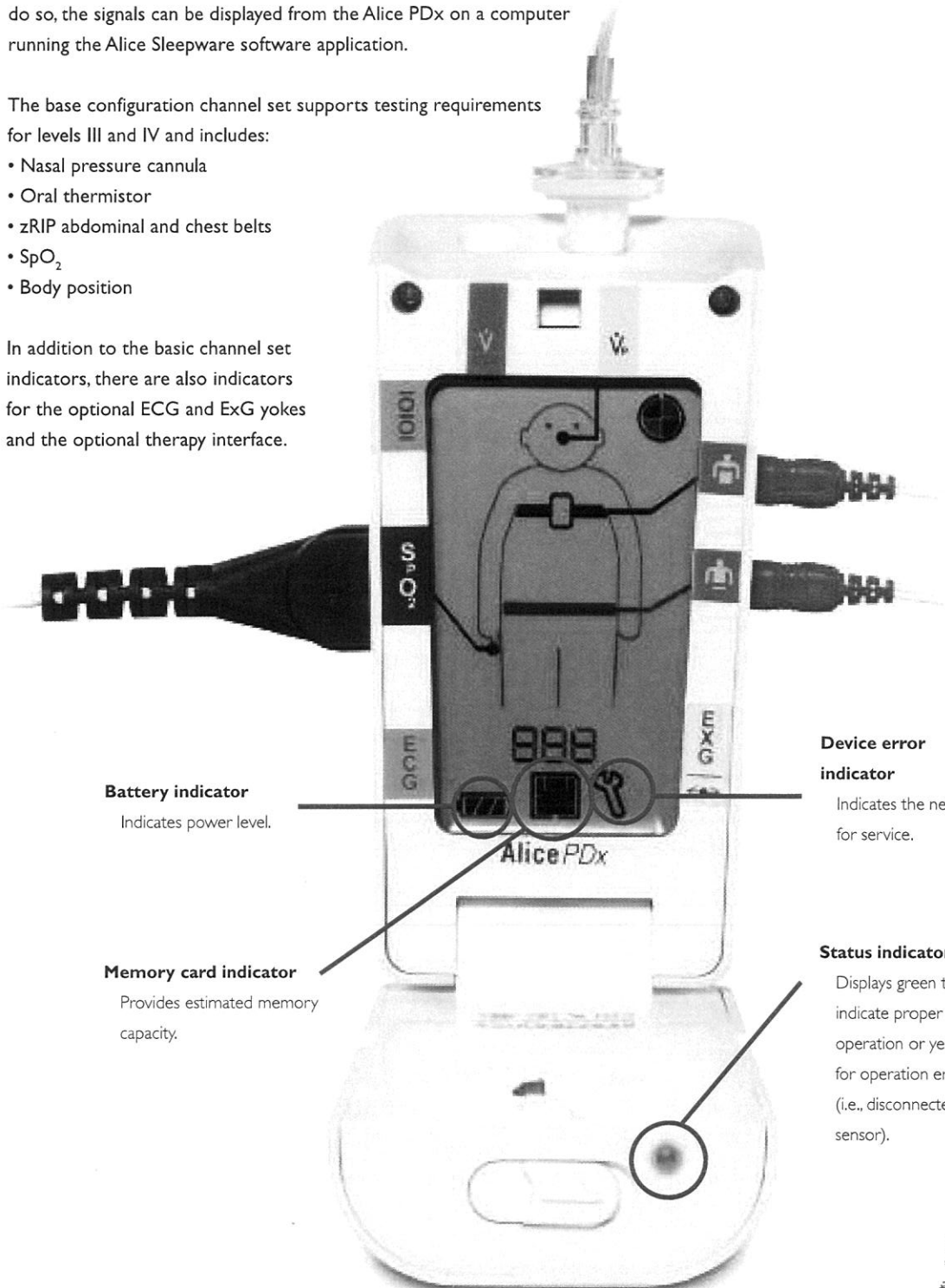
# System overview

Sensor cables transmit the appropriate signals to the Alice PDx. The signals are stored on the removable memory card, or if configured to do so, the signals can be displayed from the Alice PDx on a computer running the Alice Sleepware software application.

The base configuration channel set supports testing requirements for levels III and IV and includes:

- Nasal pressure cannula
- Oral thermistor
- zRIP abdominal and chest belts
- SpO<sub>2</sub>
- Body position

In addition to the basic channel set indicators, there are also indicators for the optional ECG and ExG yokes and the optional therapy interface.



### Battery indicator

Indicates power level.

### Memory card indicator

Provides estimated memory capacity.

### Device error indicator

Indicates the need for service.

### Status indicator

Displays green to indicate proper operation or yellow for operation error (i.e., disconnected sensor).



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<b>Software</b>	
1031854	Sleepware
<b>Training Tools:</b>	
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ExG yoke; 7 channels: 4 neuro channels (EEG or EOG) and 3 differential EMG, plus references and ground

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EMG: 2MΩ per Electrode 4MΩ differential

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EEG: 0.318Hz to 35Hz  
EMG: 9.7Hz to 86Hz

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+852 3194 2280

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For more information about the Alice PDx, visit: [www.philips.com/alicepdx](http://www.philips.com/alicepdx)

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The Alice PDx and Sleepware are prescription devices that are restricted to sale by or on the order of a physician.

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