

Alice[®] PDxTM Service & Technical Reference Manual





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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:



1001 Murry Ridge Lane Murrysville, PA 15668 USA EC REP Respironics Deutschland Gewerbestrasse 17

82211 Herrsching, Germany

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.



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SCHEMATICS



ALICE PDx INTRODUCTION

CAUTION

U.S. federal law restricts this device to sale by or on the order of a physician.

OVERVIEW

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 health care 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.

SERVICE NOTICE

The Alice PDx is designed so that qualified Service Technicians can perform repair and testing procedures. Only qualified personnel should repair this product using authorized parts.

SERVICE TRAINING

Respironics offers service training for the Alice PDx. Training includes complete disassembly of the device, troubleshooting subassemblies and components, and performance testing. For more information, contact the Respironics Service department at:

E-mail: service.operations@respironics.com Phone: (724) 755-8220 Fax: (724) 755-8230

SERVICE/TECHNICAL SUPPORT STATEMENT

For technical assistance, please contact Respironics Customer Satisfaction.

| U.S.A. and Canada | International |
|-----------------------|-----------------------|
| Phone: 1-800-345-6443 | Phone: 1-724-387-4000 |
| Fax: 1-800-886-0245 | Fax: 1-724-387-5012 |

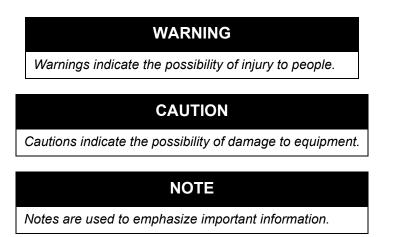


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WARNINGS, CAUTIONS, & NOTES

Warnings, cautions, and notes are used throughout this manual to identify possible safety hazards, conditions that may result in equipment or property damage, and important information that must be considered when performing service and testing procedures on the Alice PDx device. Please read this section carefully before servicing the Alice PDx.





WARNINGS

WARNINGS

- Perform Service procedures only in an ESD-protected environment.
- This device is not intended for life support.
- Do not service the Alice PDx device in a Magnetic Resonance Imaging (MRI) environment or in close proximity to a high emissions source.
- The Alice PDx system and software are not designed to replace the clinical judgement and analysis of a health care 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 service the device in the presence of a flammable anaesthetic mixture in combination with oxygen or air, or in the presence of nitrous oxide.
- When attaching the sensors and cables, be careful to route the cables in a manner that will reduce the possibility of damage to either the sensors or the device.
- Periodically inspect the sensor cables for damage or signs of wear. Replace if damaged.
- Do not immerse the Alice PDx in any fluids.
- 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.
- Do not use grease, oils, polishes or other petroleum-based products when servicing or handling the device.
- Precautionary procedures include methods to prevent buildup of electrostatic discharge (e.g., air conditioning, humidification, conductive floor coverings, and non-synthetic clothing), discharging one's body to the frame of the equipment or system or to earth or a large metal object, and bonding oneself by means of a wrist strap to the equipment or system, or to earth.

RESPIRONICS

CAUTIONS

CAUTIONS

- U.S. federal law restricts this device to sale by or on the order of a physician.
- Use only Respironics or factory-authorized replacement parts and accessories.
- 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 buildup 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 immerse the Alice PDx device in any fluids.
- 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.
- Performance of the Alice PDx cannot be assured when connected to therapy devices not manufactured by Respironics.
- If you use an ExG or EEG Neuroground, do not use the right leg/ground ECG lead.
- Never use cleaning agents or harsh 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.



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SPECIFICATIONS

PHYSICAL SPECIFICATIONS

| | 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 & Standards Compliance |
| The Alice PDx device is c | lassified as follows: |
| • Type of Protection Ag | ainst Electric Shock: Internally powered equipment. |
| Degree of Protection | Against Electric Shock: Type BF Applied part |
| Degree of protection a | against harmful ingress of water: |
| IPX0 (Ordinary pr | otection against the ingress of liquids) |
| • Mode of Operation: C | ontinuous operation |
| • Not suitable for use in | the presence of a flammable anaesthetic mixture with air, oxygen, or nitrous oxide |
| The Alice PDx device is d | esigned to conform to the following standards: |
| • IEC 60601-1, IEC 606 | 601-1-2 <i>,</i> |
| • EN 60601-1, EN 6060 | 01-1-2, UL 60601-1, CSA 22.2 No. 601.1, and AS 3200.1.0. |
| | Power Requirements |
| Three AA (1.5V) alkaline I | patteries, 0.43 watts (typ). |
| | Temperature and Storage Information |
| Temperature | Operating: 41 °F to 95 °F (5 °C to 35 °C) Storage: -4 °F to 140 °F (-20 °C to 60 °C) |
| Humidity | Operating & Storage: 15-95% (non-condensing) |
| Atmospheric Pressure | Operating & Storage: 70-102 kPa |



OPERATING SPECIFICATIONS

| | SpO ₂ |
|--------------------|---|
| Accuracy | SpO ₂ (70-100%)(± 1 SD) - |
| | No Motion: |
| | Adults: ± 2 digits |
| | Motion |
| | Adults: ± 2 digits |
| | Low Perfusion |
| | Adults: ± 2 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: ± 3 digits |
| | • Motion (40 - 240 BPM): |
| | Adults: ± 5 digits |
| | Low Perfusion (40 -240 BPM): |
| | Adults: ± 3 digits |
| | Disposal |
| Dispose of the sys | stem components in accordance with local regulations. |



ELECTROMAGNETIC EMISSIONS

This device is intended for use in the electromagnetic environment specified below. Use, service, and testing of the device should be performed in such an environment.

| GUIDANCE & MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS | | | |
|---|---|--|--|
| EMISSIONS TEST COMPLIANCE | | ELECTROMAGNETIC ENVIRONMENT GUIDANCE | |
| 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. | |
| 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 | | |



ELECTROMAGNETIC IMMUNITY

This device is intended for use in the electromagnetic environment specified below. Use, service, and testing of the device should be performed in such an environment.

| GUIDANC | GUIDANCE & MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY | | | |
|--|---|--|--|--|
| IMMUNITY TEST | IEC 60601-1-2 Test Level | COMPLIANCE LEVEL | EMC ENVIRONMENT GUIDANCE | |
| Electrical fast Transient/burst IEC 61000-4-4 | ±2 kV for power supply lines ±1 kV for I/O lines | Not applicable for battery operated devices ±1 kV for I/O lines | The 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 | The device is suitable for use in all establishments, including domestic establishments. | |
| 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 | The device is suitable for use in all establishments, including domestic establishments. | |



| GUIDANC | GUIDANCE & MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY | | | |
|-------------------------------|--|---------------------|---|--|
| Immunity Test | IEC 60601-1-2 Test Level | Compliance Level | EMC ENVIRONMENT GUIDANCE | |
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | 3 Vrms | Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation | |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3 Vrms | 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 P = maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d =$ 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 reorienting 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 & MOBILE RF COMMUNICATIONS AND THE M SERIES BASE PLATFORM SLEEP THERAPY DEVICES

This device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Electromagnetic interference may be prevented by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this device as recommended in the table 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 | 80 MHz to 800 MHz | 800 MHz to 2.5GHz |
| | $d = 1.2\sqrt{P}$ | $d = 1.2\sqrt{P}$ | $d = 2.3\sqrt{P}$ |
| 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.



THEORY OF OPERATION

OVERVIEW

A block diagram of the Alice PDx system is shown in Figure A.

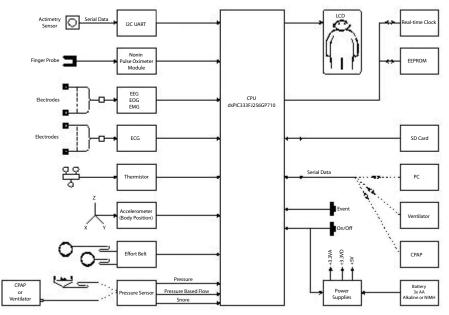


FIGURE A: SYSTEM DIAGRAM

The system consists of a microcontroller, operating under program control, which collects signal inputs from the various peripheral signal conditioning circuits and stores that information on a removable data storage media. The system provides a User Interface (UI), which consists of a Liquid Crystal Display (LCD), an Event push button and a Power push button. A serial data link port, capable of communicating with external devices such as a Personal Computer (PC), or, various Respironics CPAP and Ventilator products is provided.

The Alice PDx is housed in a two-piece, hinged plastic housing. A removable cover on the back side of the housing allows user access for replacement of the three "AA" cells, which provide power for the unit. The same cover also allows access to the removable data storage card.

All of the electrical circuitry is contained on three PCAs, broken down as follows:

- Analog PCA
- Digital PCA
- Battery PCA

A detailed explanation of the circuitry on each PCA will follow.



DETAILED CIRCUIT DESCRIPTIONS

ANALOG PCA

ECG

NOTE

Refer to Alice PDx Analog Board Schematics sheets 1, 2, and 3, located in the Schematics section beginning on page 53.

The ECG subsystem consists of three signal conditioning circuits that receive biopotential signals from electrodes on the patient's body and convert them to signals suitable for application to the ADC in the microcontroller. All three channels provide identical gain and frequency response and differ only in input connections.

All ECG signal conditioners are designed to the following parameters:

- Input voltage range: +/-4 mVDC
- Input coupling type: DC
- Input impedance: 10 Megohm single-ended, 20 Megohm differential
- Bandwidth: 0.318Hz to 200Hz (-3 dB)
- Output voltage range: 0 to 3VDC
- Quiescent output voltage: 1.5VDC
- Total gain: 375

The three ECG channels are ECG-I, ECG-II and ECG-V. Since each of the three signal conditioners contain identical circuitry, only ECG-I will be discussed here.

In a normal configuration, electrodes are placed on the patient in the following locations: left arm, right arm, left leg, right leg and chest. ECG-I measures the potential between the left arm and the right arm. ECG-II measures the potential between the left leg (+) and the right arm (-). ECG-V measures the potential between the chest electrode (+) and the average voltage of the left arm, right arm and left leg electrodes. Other ECG channels (known as "leads") can be derived by the algebraic addition and subtraction of the various channels by software running in the microcontroller, or in the host computer.

Signal from the patient electrodes enter the Alice PDx unit at J16-1 (left arm) and J16-3 (right arm) and passes through R1 and R21, which in conjunction with C7 and C22, form lowpass filters for EMC susceptibility reduction. A Transient Voltage Suppressor (CR4) and conventional diodes CR1A and CR1B provide ESD protection. Resistors R18 and R20 bias the left and right arm signals approximately 1.5 VDC to ensure these signals are within the common mode range acceptable to U9.

Amplifier U9 is a low-drift instrumentation amplifier which amplifies the difference between the left and right arm signals by a factor of 18.7.

The output of U9 is fed to a four pole lowpass active filter formed by U10A and U10B. This filter has a cutoff frequency (Fc) of 200 Hz (-3dB) and a gain of 20. This filter was designed to have low phase distortion, to prevent distortion of the ECG waveform. The filtered signal is buffered by amplifier U10D prior to being sent to the microcontroller ADC.

Amplifier U10C forms an integrator which is used to remove any DC shift that may occur in the amplifier/filter chain. The integrator has a Tc of 10 seconds and feeds back into the reference input of instrumentation amplifier U9. The integrator causes the signal at the output of U10B to be centered about ANALOG_REF, even

PAGE 14



if a DC shift occurs due to amplifier offsets or a small DC offset occurring in the signal input. The action of the integrator causes the appearance of a single pole of highpass filtering with a cutoff frequency of 0.318 Hz to appear in the response of the ECG signal conditioning circuit.

EEG/EOG

NOTE

Refer to Alice PDx Analog Board Schematic sheets 4, 5, and 6, located in the Schematics section beginning on page 53.

The EEG signal conditioners serve to amplify and filter the low-level "brain-wave" signals picked up by electrodes placed on the scalp of the patient such that they are suitable for application to the microcontroller ADC. There are a total of 5 EEG amplifiers in the Alice PDx system. They are:

- EEG N1 R1
- EEG N2 R1
- EEG N3 R2
- EEG N4 R2
- EEG R1 R2

All EEG signal conditioners are designed to the following parameters:

- Input voltage range: 1000 µVp-p
- Input coupling type: AC
- Input impedance: 2 Megohm single-ended, 4 Megohm differential
- Bandwidth: 0.08 Hz to 35 Hz (-3 dB)
- Output voltage range: 0 to 3 VDC
- Quiescent output voltage: 1.5 VDC
- Total gain: 3000

Since all five signal conditioners function identically, with the exception of their input connections, the operation of only one amplifier will be described here.

Signal from the electrodes enters the Alice PDx at J7-1 and J7-2 and pass through EMC/ESD protection components CR19B, R209, C30, CR18A, C32, R210, C129, C130 and C132. The signal then passes through a highpass RC filter consisting of C158, R63, C159 and R64. This filter serves to remove any DC offset due to electrogalvanic action of the electrodes and has a cutoff frequency of 0.08 Hz. The signal is amplified by instrumentation amplifier U1 with a gain of 150.

The amplified signal then passes to a four-pole active filter composed of amplifiers U2A and U2B. This filter has a gain of 20, a cutoff frequency of 35 Hz, and is designed to minimize phase distortion of the signal.

The filtered signal next travels to amplifier U2D, where it is buffered prior to being sent to the analog input of the system microcontroller.

A sample of the filtered signal is sent to an integrator formed by U2C. The output of the integrator feeds the reference pin of U1 and causes the output of U2B to have a quiescent voltage equal to ANALOG_REF, thus, removing any DC offset due to amplifier offsets.



EOG

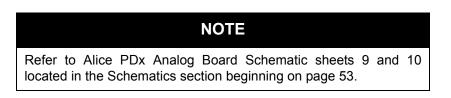
NOTE

Refer to Alice PDx Analog Board Schematic sheets 7 and 8, located in the Schematics section beginning on page 53.

Alice PDx contains three EMG signal conditioners which function identically to the EEG signal conditioners, but, are designed to different parameters. All EMG signal conditioners are designed to the following parameters:

- Input voltage range: 300 uVp-p
- Input coupling type: AC
- Input impedance: 2 Megohm single-ended, 4 Megohm differential
- Bandwidth: 10 Hz to 100 Hz (-3 dB)
- Output voltage range: 0 to 3 VDC
- Quiescent output voltage: 1.5 VDC
- Total gain: 10,000

EFFORT BELT



The operation of effort belt #1 is identical to that of #2, therefore, only the operation of belt #1 will be explained here.

An elastic belt which has wire woven through it is wrapped around the patient's abdominal or thoracic area. As the patient breathes, the diameter of the patient's abdomen or thorax changes, causing a change in the belt diameter. Any change in the belt diameter causes a change in the belt's inductance. The belt inductance, in concert with C75 and C85 form a resonant circuit which controls the frequency of a Pierce oscillator formed with U19. As the belt inductance changes, so does the frequency of oscillation. The nominal frequency of oscillation of Belt #1 is approximately 100 KHz while Belt #2 is 170 KHz. These nominal frequencies can vary over a wide range, depending on the inductance of the effort belt.

The nominal belt inductance is approximately 42 uH. This test was performed on a few belts that were available at the time of test and may not be indicative of inductance values to be expected in other belt samples.

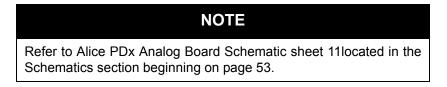
The output of oscillator U19 is fed into U20, an LM555CM timer chip operating as a oneshot multivibrator. In this mode, every falling edge of the signal from U19 causes U20 to output a positive pulse of a fixed duration of approximately 1.4 usec. U20 will change the rate at which it is triggered, due to changes in U19 frequency. This change of trigger rate, when taken with a constant duration pulse output by U20 each time it is triggered, means the duty cycle of U20's output changes in response to changes in U19's oscillation frequency. U20's output pulses are low pass filtered in a network formed by R165, R166, R167, C103, C104 and C105. After filtering, a DC voltage is obtained which is proportional to the frequency of oscillation of U19. Since U19's frequency of oscillation is controlled by the inductance of the effort belt, we now have derived a voltage whose value is dependent upon the inductance of the effort belt.



The DC voltage obtained across C105 is fed to amplifiers U21A and U21B via capacitor C117. C117 removes any DC offset that may be present in the belt signal while U21 amplifies the signal to a level suitable for application to the ADC.

It should be noted that the effort belt signals are fed to the LTC1867L 16 bit ADC, rather than the internal ADC of the microcontroller. This was done because it was felt that respiratory signal would need a greater dynamic range than other signals.

PRESSURE/SNORE/RESPIRATION SENSOR



The pressure sensor in Alice PDx allows the measurement of pressure at the patient's mask due to a CPAP or ventilator, and the detection of both snore and respiration via the use of a nasal cannula.

When a pressure tap is connected from the Alice PDx to the patients' mask, pressure over the range of -5 to 40 CM can be read from the sensor into the microcontroller via the sensor's I2C port.

When a cannula is connected, patient snore and respiration signals are detected by using a direct connection from the sensor's bridge output pins, which is amplified in instrument amplifier U18. Here, the differential voltage is amplified by a gain of 82.

The amplified signal is then fed to two sets of amplifier/filter circuits for deriving the respiration and snore signals.

The respiration signal is detected by taking the U18 output and passing it first through a single pole RC filter consisting of C81 and R17. This filter has a cutoff frequency of 0.03 Hz. The signal is then amplified by a factor of 3.15 by U17A. The respiration signal passes through a 15 Hz, 2 pole active filter, consisting of U17B and associated components. The amplified and filtered signal is then sent to the LTC1867L 16 bit ADC (U30) on the digital board.

The output of amplifier U18 also feeds the snore detection circuit. The amplified signal. Passes through U23A, where it is highpass filtered at 100 Hz and amplified with a voltage gain of 50. The filtered signal next passes through U23B, which is configured as a gain of 1 inverting amplifier. This amplifier configuration was chosen to provide a simple way to increase the gain of the signal path, if needed, simply by changing the values of resistors R27 and R12. U23C and U23D provide additional voltage gain (8) and lowpass filtering (180 Hz) of the signal, prior to application to the analog to digital converter U30, located on the digital board.

The pressure sensor used in the Alice PDx offers extremely stable performance over a wide range of temperatures. Stability of the sensor is enhanced by an onboard temperature sensor and DSP that correct the sensor's output as needed, to limit error to +/-2% over the temperature range of 0 - 60 °C.

Since the digital output of the sensor is only updated at a rate of <100 Hz and is limited to 12 bits, it was necessary to gain access directly to the bridge outputs and apply external signal processing to obtain the snore and respiration signals.



DIGITAL PCA

MICROCONTROLLER

NOTE

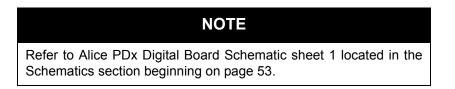
Refer to Alice PDx Digital Board Schematic sheet 3 located in the Schematics section beginning on page 53.

The system microcontroller is a Microchip dsPIC33FJ256GP710. Key features of this part include:

- 256 KB Flash program memory
- 32 Kbytes static RAM
- 32 Analog inputs
- 2 UARTS
- 2 SPI ports
- 2 I2C ports
- The ability to access many peripherals via DMA

The microcontroller is responsible for coordinating the operation of Alice PDx system. Analog signals are received from the various sensors and processed by their respective conditioning circuits. These signals are then passed to the microcontroller where they are further processed for storage on the SD memory card.

THERMISTOR CIRCUIT



The thermistor circuit provides the interface between a nasal or oral thermistor and the system microcontroller. Current flow through the thermistor, via resistor R137 causes a voltage to be developed across the thermistor. Slight variations will occur in the voltage across the thermistor in response to resistance changes due to patient respiration. These voltage variations will be coupled through a low pass filter, consisting of R155 and C50 and then through a highpass filter consisting of R145 and C210. The filtered signal is then amplified by U38A and low pass filtered by R293 and C211 before being sent to the LT1867L 16 bit ADC.

A THERM_GOOD signals the microcontroller when a plug is inserted into jack J6.

- Amplifier gain: 31
- Lowpass filter cutoff: 16 Hz
- Highpass filter cutoff: 0.033 Hz



BODY POSITION SENSOR (ACCELEROMETER)

NOTE

Refer to Alice PDx Digital Board Schematic sheet 1 located in the Schematics section beginning on page 53.

A three-axis accelerometer mounted on the digital board provides body position sensing by means of determining the sensor's attitude with respect to gravity. The accelerometer is oriented such that:

- X is in the vertical axis
- Y is in the horizontal axis
- Z is in the front-to-back axis

16-BIT ANALOG TO DIGITAL CONVERTER

NOTE Refer to Alice PDx Digital Board Schematic sheet 1 located in the Schematics section beginning on page 53.

A standalone 16 bit ADC (U30) was included to provide the high resolution needed for sensing respiratory signals. The LTC1867L provides for up to 8 input channels, only four of which are used. The ADC communicates with the system microcontroller via an SPI port.

The ADC's internal reference is disabled and the device fed with an external 3.0 VDC reference.

ANALOG REFERENCE SUPPLY

Refer to Alice PDx Digital Board Schematic sheet 1.

The analog reference supply provides a voltage that is equal to VREF * ½ to all of the analog circuitry on the digital and analog boards. This ensures that the quiescent outputs of all of the signal conditioners throughout the system are held at one half the input range of the system ADCs.

POWER SUPPLIES

NOTE

Refer to Alice PDx Digital Board Schematic sheet 2 located in the Schematics section beginning on page 53.

Battery voltage is converted to the various operating voltages needed by the Alice PDx by means of three DC to DC converter circuits. These circuits supply operating voltage to the +3.3V_DIG, +3.3V_ANA and +5V busses.

Battery voltage can vary from zero volts, for a fully discharged battery, to about 4.8 VDC, for a fully charged battery. This poses special problems for the +3.3V supplies, as the input voltage can be less than, equal to, or, greater than the output voltage, requiring different power supply topologies as battery voltage changes. The IC chosen for the 3.3 VDC supplies is the LTC3440, by Linear Technologies. This part automatically reconfigures itself as either a buck or boost converter, as needed to maintain voltage regulation.



There are separate supplies for both the +3.3V_ANA and +3.3V_DIG busses, consisting of U24 and U25, respectively.

A third DC to DC converter, U6, supplies power to the +5V bus. In this case, output voltage would always be higher than input voltage, allowing the use of a boost-only converter topology. The part chosen for this circuit was the LT3526B, by Linear Technologies.

The original circuit for the +5V supply was an ON Semiconductor NCP1421. While highly efficient, this part generated a rather noisy +5V supply. Since the +5V supply feeds the pressure sensor, noise on the +5V bus was appearing on the snore signal, lowering the signal to noise ratio of the snore signal. The +5V supply was changed to the LT2526B in order to improve the signal to noise ratio of the snore signal.

Amplifier U39 provides an indication of battery voltage to the microcontroller. The output of U39 (Vbatt) follows the relationship below:

Y = MX + B

Where:

Y = voltage measured directly on the battery terminals

M = 1.922

X = VBATMON

B = 0.4212

The battery monitoring circuits are located on the digital board, rather than on the battery board. As a result, the battery monitoring circuit must measure battery voltage after it has passed through a considerable amount of resistance, due to traces in the flex circuit, EMC choke coils, and other devices. Main power for the unit also passes through these resistances, causing voltage drops to develop between the battery and the battery monitoring circuit. The equation above accounts for these voltage drops, assuming the device is drawing a nominal load current of about 78 mA. If load current should deviate from this value, it may be necessary to recalculate the M and B constants.

The system processor monitors VBATMON and will issue a low battery warning when the battery terminal voltage falls below approximately 3.1 volts. The low battery warning will cause the system to halt further accesses to the SD card, as well as flash the battery icon on the LCD.

If the battery continues to drain to a terminal voltage approximately 2.82 volts, battery supervisor U7 will issue a "battery critically low" warning to the processor via the BATT_GOOD line. This will cause the processor to go into an immediate system shutdown. Due to the voltage drops mentioned above, it was necessary to set the trip point of the voltage supervisor to 2.55 volts.

The control circuit for the power supplies is shown on sheet 6 of the Digital Board Schematic.

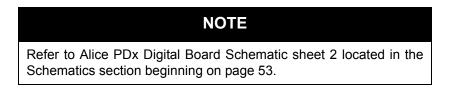
When the power button is pressed, a logic low appears at the /PR input of D-type flip flop U17, which puts the flip flop into the preset state. When in the preset state, output /Q is at logic low, which causes MOSFETS Q3A and Q3B to not conduct, enabling the power supplies. A similar condition can be achieved if the RTC (U5) pulses the /IRQ/FOUT pin low in response to the passing of a preset time condition.

While any further presses of the power button have no direct effect on the power control circuit, the microcontroller is notified of button pushes via a port pin. This button push may be detected by the program running in the microcontroller and cause the microcontroller to initiate a shutdown of the power system. When the microcontroller places a logic high on the gate of Q2A, flip flop U17 is forced into the CLEARED state, applying a logic high on MOSFETS Q3A and Q3B, which causes a shutdown of the power supplies.



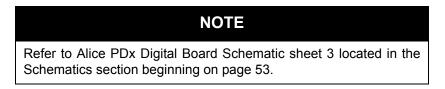
Under this scheme, the microcontroller can initiate a shutdown not only in response to a user request, but anytime it is necessary. A weak battery, or, a detected malfunction in the unit may be cause for a system shutdown.

ACTIMETRY UART (U1)



A UART (Universal Asynchronous Receiver Transmitter), which is accessible to the microcontroller via an I2C port is provided to support a future external actigraphy sensor.

ANALOG VOLTAGE REFERENCE



A precision 3.0 VDC reference is provided to the microcontroller ADC and the 16 bit external ADC (U30) by the analog reference regulator (U13). ANALOG_REF is also derived from this signal.

NON-VOLATILE DATA STORAGE

NOTE Refer to Alice PDx Digital Board Schematic sheet 3 located in the Schematics section beginning on page 53.

32 Kbytes of non-volatile data storage is provided by EEPROM U4.

Additional Data Storage

NOTE

Refer to Alice PDx Digital Board Schematic sheet 3 located in the Schematics section beginning on page 53.

32 Kbytes of additional temporary data storage is provided by U36. This RAM memory is accessed by an SPI port.



LCD DRIVER

NOTE

Refer to Alice PDx Digital Board Schematic sheet 5 located in the Schematics section beginning on page 53.

The microcontroller communicates with the LCD via I2C port 2. The 3.3 volt logic levels of the microcontroller are translated by U2 to the 5 volt levels as required by the off board LCD. The LCD contains its own PCA8576 driver on the LCD glass.

BATTERY PCA

NOTE

Refer to Alice PDx Battery Board Schematic sheet 1 located in the Schematics section beginning on page 53.

BATTERIES

Power for the Alice PDx is provided by three user-replaceable "AA" size cells which are mounted by means of spring clips to the battery board. While the preferred cell chemistry is either alkaline or NiMH, it is recognized that chemistries other than the preferred ones may be used. While these alternate chemistries may not provide ideal performance, they should not cause damage to the Alice PDx or the batteries and must not cause a hazardous condition to occur.

OVERCURRENT PROTECTION

Overcurrent protection is provided by positive temperature coefficient thermistor F1.

REVERSE POLARITY PROTECTION

Protection of the device from the application of reverse polarity is provided by P-channel MOSFET Q1. An RC network at the gate of Q1 provides a slow turn-on of power to the VBATT bus. This slow turn-on feature limits the charging current to capacitors on the input of the DC to DC converters (digital board) enough to prevent damage to MOSFET Q1.

SD CARD

The battery board contains the socket for the SD card.

INDICATOR LED

The battery board contains a bi-color (yellow/green) LED as part of the user interface. Inverters U1 and U2 provide drive current to the LEDs, as commanded by the microcontroller.



TROUBLESHOOTING

This troubleshooting guide provides a method for identifying the cause of a failure.

COMMON PROBLEMS

| PROBLEM | POSSIBLE CAUSES | CORRECTIVE ACTION |
|--------------------------------|----------------------------|---|
| Unit will not power up | Loose flex cable | Replace flex cable |
| | Faulty Battery PCA | Replace Battery PCA – check P5 connector and F1 (less than 1 ohm) |
| | Faulty Digital PCA | Replace Digital PCA – check P4 connector |
| Empty Battery Icon flash | Battery Low | Replace Batteries |
| Yellow LED flash | | Replace Battery PCA |
| Memory Card outline icon flash | Memory Card Missing or Bad | Replace Memory Card |
| Yellow LED flash | | Replace Battery PCA |
| | | Replace Digital PCA |
| Full Memory Card Icon Flash | Memory Card Full | Empty Memory Card |
| Yellow LED Flash | | |
| Wrench Icon Flash | Safe Error State | Access error log |
| Yellow LED Flash | | |

ERROR CODE TABLE

| | PDx Events | | | | |
|---------------|---|--------------------|---------------------|--|--|
| Error Code | DESCRIPTION | PROBABLE CAUSE | CORRECTIVE ACTION | | |
| 12 | Configuration Component EEPROM Update Failed | Faulty Digital PCA | Replace Digital PCA | | |
| 13 | Failed to get Configuration Component | Faulty Digital PCA | Replace Digital PCA | | |
| 21 | Reserved (Unused) | Faulty Digital PCA | Replace Digital PCA | | |
| 31 | Reserved (Unused) | Faulty Digital PCA | Replace Digital PCA | | |
| 32 | Reserved (Unused) | Faulty Digital PCA | Replace Digital PCA | | |



| | CRITICAL ERRORS | | | |
|---------------|--|--|---|--|
| Error Code | DESCRIPTION | PROBABLE CAUSE | CORRECTIVE ACTION | |
| 150 | Reserved (Unused) | Faulty Digital PCA | Replace Digital PCA | |
| 151 | Boot Monitor Software Program CRC Test Failed | Software memory corrupted | Update Software Replace Digital PCA | |
| 152 | Main Application Software Program CRC Test Failed | Software memory corrupted | Update Software Replace Digital PCA | |
| 153 | SRAM Data Bus Test Failed | Faulty Digital PCA | Replace Digital PCA | |
| 154 | SRAM Address Bus Test Failed | Faulty Digital PCA | Replace Digital PCA | |
| 155 | SRAM Data Location Test Failed | Faulty Digital PCA | Replace Digital PCA | |
| 156 | Watchdog Timer Check Test Failed | Faulty Digital PCA | Replace Digital PCA | |
| 158 | Watchdog Timer Timeout | Faulty Digital PCA | Replace Digital PCA | |
| 159 | Stack Overrun Test Failed | Faulty Digital PCA | Replace Digital PCA | |
| 160 | Main Battery Check Low Battery | Faulty Battery PCA Loose flex cable Faulty Digital PCA | Replace Battery PCA Replace flex cable Replace Digital PCA | |
| 161 | Microcontroller Exception Detected | Faulty Digital PCA | Replace Digital PCA – check U29 | |
| 162 | Spurious Unused/Interrupt Detected | Faulty Digital PCA | Replace Digital PCA – check U29 | |
| 163 | Software Exception Detected | Faulty Digital PCA | Replace Digital PCA – check U29 | |
| 164 | OS Error Detected | Faulty Digital PCA | Replace Digital PCA – check U29 | |
| 165 | SD Card Write Protected | Wrong SD card status (write protected) Faulty Battery PCA Loose flex cable Faulty Digital PCA | Replace SD card Replace Battery PCA Replace flex cable Replace Digital PCA | |



| | CRITICAL ERRORS | | | |
|---------------|----------------------------------|--|--|--|
| Error Code | DESCRIPTION | PROBABLE CAUSE | CORRECTIVE ACTION | |
| 166 | SD Card Removed Error | Wrong SD card status (write protected) Faulty Battery PCA Loose flex cable Faulty Digital PCA | Replace SD card Replace Battery PCA Replace Clamshell Assembly Replace Main PCA Stack | |
| 167 | SD Card Full | Wrong SD card status (write protected) Faulty Battery PCA Loose flex cable Faulty Digital PCA | Replace SD card Replace Battery PCA Replace Clamshell Assembly Replace Main PCA Stack | |
| 168 | SD Card I/0 Error | Wrong SD card status (write protected) Faulty Battery PCA Loose flex cable Faulty Digital PCA | Replace SD card Replace Battery PCA Replace Clamshell Assembly Replace Main PCA Stack | |
| 169 | Initialization Error | Faulty Digital PCA | Replace Main PCA Stack | |
| 170 | EEPROM I/O Error | Faulty Digital PCA | Replace Main PCA Stack | |
| 171 | Comm Port I/O Error | Faulty Digital PCA | Replace Digital PCA | |
| 174 | Serial RAM I/O Error | Faulty Digital PCA | Replace Main PCA Stack – check U36 | |
| 175 | Pressure Sensor Error | Faulty Analog PCA Loose Pressure connection | Replace Main PCA Stack | |
| 176 | LCD controller Error | Faulty LCD Faulty Digital PCA | Replace LCD Replace Main PCA Stack | |
| 177 | Watchdog Test RAM Error | Faulty Digital PCA | Replace Main PCA Stack | |
| 178 | Serial SRAM Data Bus Test Failed | Faulty Digital PCA | Replace Main PCA Stack – check U36 | |



| | CRITICAL ERRORS | | | |
|---------------|--|--------------------|---------------------------------------|--|
| Error Code | DESCRIPTION | PROBABLE CAUSE | CORRECTIVE ACTION | |
| 179 | Serial SRAM Address Bus Test Failed | Faulty Digital PCA | Replace Main PCA Stack – check U36 | |
| 180 | Serial SRAM Data Location Test Failed | Faulty Digital PCA | Replace Main PCA Stack – check U36 | |

| | Non-Critical Errors | | | |
|---------------|---|---|--|--|
| Error Code | DESCRIPTION | PROBABLE CAUSE | CORRECTIVE ACTION | |
| 226 | Body Position Sensor (Accelerometer) Test Failed | Faulty Digital PCA | Replace Main PCA Stack – check U18 | |
| 227 | RTC I/O Error | Faulty Digital PCA | Replace Main PCA Stack – check U5 | |
| 228 | RML Event Buffer Overflow | Faulty Digital PCA | Replace Main PCA Stack | |
| 229 | EEPROM Manufacturing Data Checksum Failure | Faulty Digital PCA | Replace Main PCA Stack | |
| 230 | SpO2 I/O Error | Faulty Oximetry Module Faulty Digital PCA Faulty Analog PCA | Replace Main PCA Stack | |
| 231 | Reboot Limit Exceeded | Faulty Digital PCA | Replace Digital PCA | |
| 232 | SpO2 Lost Synch Error | Faulty Oximetry Module Faulty Digital PCA Faulty Analog PCA | Replace Oximetry Module Replace Digital PCA Replace Analog PCA | |
| 233 | SpO2 Frame Error | Faulty Oximetry Module Faulty Digital PCA Faulty Analog PCA | Main PCA Stack | |
| 234 | RTC Test Failed | Faulty Digital PCA | Replace Main PCA Stack – check U5 | |



| | Non-Critical Errors | | | | |
|---------------|--|--------------------|---------------------------------------|--|--|
| Error Code | DESCRIPTION | PROBABLE CAUSE | CORRECTIVE ACTION | | |
| 235 | Body Position Sensor (Accelerometer) Test Data Update Error | Faulty Digital PCA | Replace Main PCA Stack – check U18 | | |
| 236 | UART1 Error | Faulty Digital PCA | Replace Main PCA Stack | | |
| 237 | TD Missed Sample Error | Faulty Digital PCA | Replace Main PCA Stack | | |
| 238 | EEPROM HW Data Checksum Failed | Faulty Digital PCA | Replace Main PCA Stack | | |



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REPAIR AND REPLACEMENT

For technical assistance or replacement part ordering information, contact Respironics Product Support.

USA and Canada

Phone: 1-800-345-6443 Fax: 1-800-866-0245 Email: service@respironics.com

International

Phone: 1-724-387-4000 Fax: 1-800-387-5012



RP KIT REFERENCE TABLE

| KIT CONTENTS | PART NO. |
|---|---|
| Galaxy Analog Board PCA | 1054921 |
| Galaxy Digital Board PCA | |
| Pulse Ox Module | |
| • 4-40 Phil Screw | |
| • Flat washer (x3) | |
| • 3/16" Nylon Standoff | |
| Thermistor Foam | |
| Battery PCA | 1054922 |
| Battery Door | 1053279 |
| Battery enclosure | 1054948 |
| • #2 torx pan plastite 5/16" long (4x) | |
| • #2 torx pan plastite 5/16" long (4x) | 1054949 |
| Battery PCA Flex Cable | 1055426 |
| • LCD | 1055427 |
| • Hinge Cup | |
| Display Holder | 1055428 |
| Display enclosure cover | 1054923 |
| Cannula and Cannula Cover | (Domestic U.S. and Japan) |
| • Hinge, Clamshell w/Detent | |
| • Base lock | |
| Power button | 1051001 |
| • Lock hook | 1054924 (International) |
| • Spring, compression, 0.079" OD, 3.81lb/in | (|
| • Flex cable | |
| Plug, large (2x) | 1054925 |
| • Plug, small (2x) | |
| Power Button | 1055429 |
| Display Enclosure | 1054926 |
| Event Button | |
| Display Enclosure | 1054947 |
| Event Button | |
| • Screw, #2 phil, pan. plastite. 3/4" long (2x) | 1054950 |
| , , , , , , , | |
| | Galaxy Analog Board PCA Galaxy Digital Board PCA Pulse Ox Module 4-40 Phil Screw Flat washer (x3) 3/16" Nylon Standoff Thermistor Foam Battery PCA Battery Door Battery enclosure #2 torx pan plastite 5/16" long (4x) #2 torx pan plastite 5/16" long (4x) Battery PCA Flex Cable LCD Hinge Cup Display enclosure cover Cannula and Cannula Cover Hinge, Clamshell w/Detent Base lock Power button Lock hook Spring, compression, 0.079" OD, 3.81lb/in Flex cable Plug, large (2x) Plug, small (2x) Power Button Display Enclosure Event Button Display Enclosure Event Button Display Enclosure |



| Additional Accessories | | |
|------------------------|------------------|---------|
| Holster | Holster | 1053280 |
| 1GB SD card, 2-pack | 1GB SD Card (x2) | 1053952 |

BENCH CHECKOUT

Prior to performing service procedures on the Alice PDx, perform the following:

- 1. Visually inspect the outside of the device for physical damage and broken or missing parts.
- 2. Power on the device and verify that self test begins.
- 3. Perform repairs to the device as necessary.
- 4. Conduct the Performance Verification/Post-service Testing Procedure on page 47.



REPLACEMENT PROCEDURES

CAUTION

Repair this device only in an ESD-protected environment.

NOTE

Upon replacing any component, you must perform the Performance Verification/Post-Service Testing procedure. Refer to page 47 for required testing after component replacement.

REPLACING THE BATTERY DOOR & BATTERIES

To remove the Battery Door & Batteries:

- 1. Slide the Battery Door away from the Battery Enclosure as shown in the following illustration.
- 2. Remove the Batteries from the Battery Enclosure.

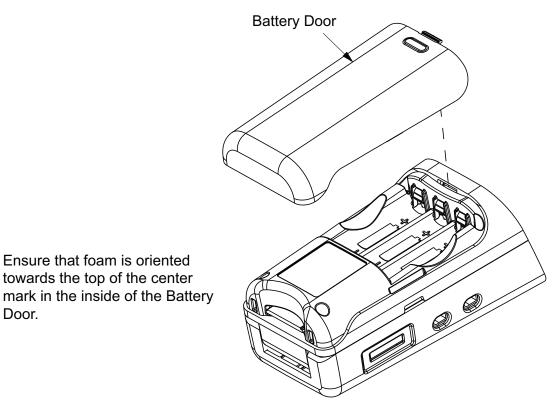


FIGURE B: REMOVING AND INSTALLING THE BATTERY DOOR

To install the Battery Door:

Door.

Align the Battery Door locking tab with the slot in the Battery Enclosure and slide the Battery Door into place.



REPLACING THE BATTERY ENCLOSURE

To replace the Battery Enclosure:

- 1. Using a Torx T8 screwdriver, remove and retain the four screws that secure the Battery Enclosure to the Clamshell Assembly.
- 2. Lift the Battery Enclosure away from the Battery PCA/Battery Enclosure Cover Assembly. Refer to the following illustration.

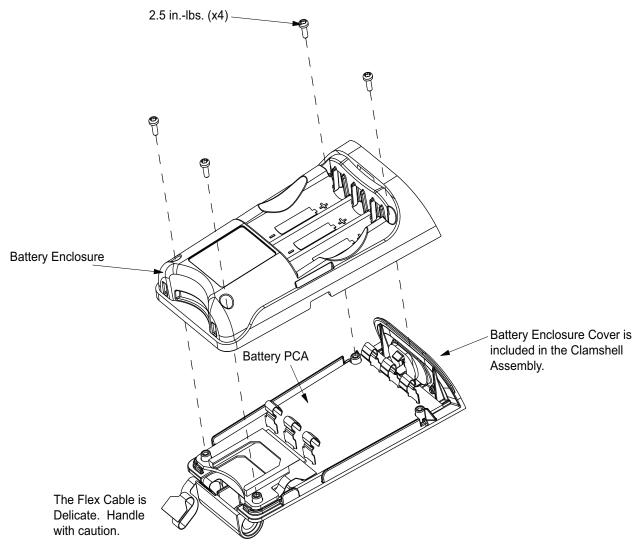


FIGURE C: BATTERY ENCLOSURE REMOVAL

To install the Battery Enclosure:

- 1. Be sure the Battery PCA is properly seated in the Battery Enclosure Cover.
- 2. Align the Battery Enclosure with the Battery PCA/Battery Enclosure Cover Assembly and properly seat the Battery Closure in place.
- 3. Secure the Battery Enclosure with the four screws previously removed.



REPLACING THE BATTERY PCA

To remove the Battery PCA:

1. Disconnect the Ribbon Cable from the P5 Connector on the Battery PCA.



2. Lift the Battery PCA out of the Clamshell Assembly. Refer to the following illustration.

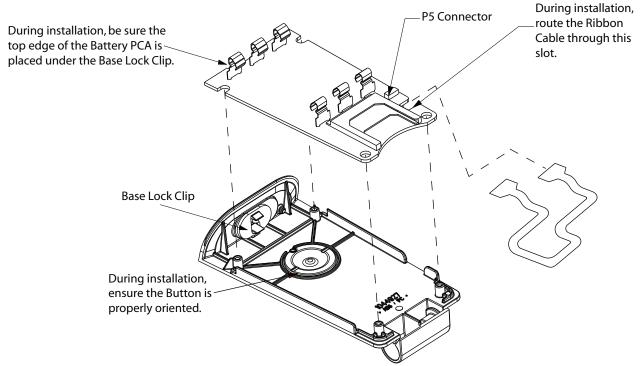


FIGURE D: BATTERY PCA REMOVAL/REPLACEMENT (ENTIRE CLAMSHEELL ASSEMBLY NOT SHOWN)

To install the Battery PCA:

- 1. Be sure the Power Button is properly oriented in the Battery Enclosure Cover and that the Ribbon Cable is properly routed through the slot in the Battery PCA.
- 2. Align the Battery PCA with the Battery Enclosure Cover. Refer to Figure D.
- 3. Connect the Ribbon Cable to the P5 connector on the Battery PCA.
- 4. Assemble the remainder of the Alice PDx as necessary.



Replacing the Power Button

To remove the Power Button:

- 1. Remove the Battery Door and Batteries. Refer to page 32 for removal instructions if necessary.
- 2. Remove the Battery Enclosure. Refer to page 33 for removal instructions if necessary.
- 3. Remove the Battery PCA. Refer to page 34 for removal instructions if necessary.
- 4. Lift the Power Button out of the Battery Enclosure Cover (part of the Clamshell Assembly).

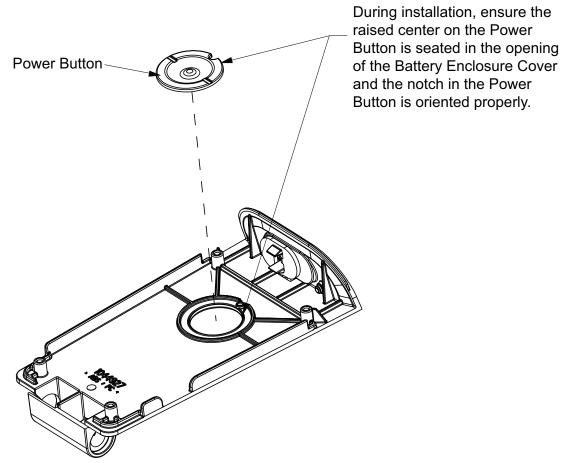


FIGURE E: POWER BUTTON REMOVAL/INSTALLATION (ENTIRE CLAMSHEELL ASSEMBLY NOT SHOWN)

To install the Power Button:

- 1. Place the Power Button in the opening of the Battery Enclosure Cover. Ensure the raised center of the Button is seated in the opening of the Battery Enclosure Cover and the Button's notch is properly oriented.
- 2. Assemble the remainder of the Alice PDx as necessary.



REPLACING THE DISPLAY ENCLOSURE

To remove the Display Enclosure:

- 1. Open the Alice PDx to expose the LCD.
- 2. Remove the four Rubber Mounts to expose the four screws that secure the Display Enclosure to the Display Enclosure Cover.
- 3. Remove the four screws that secure Display Enclosure to the Display Enclosure Cover.

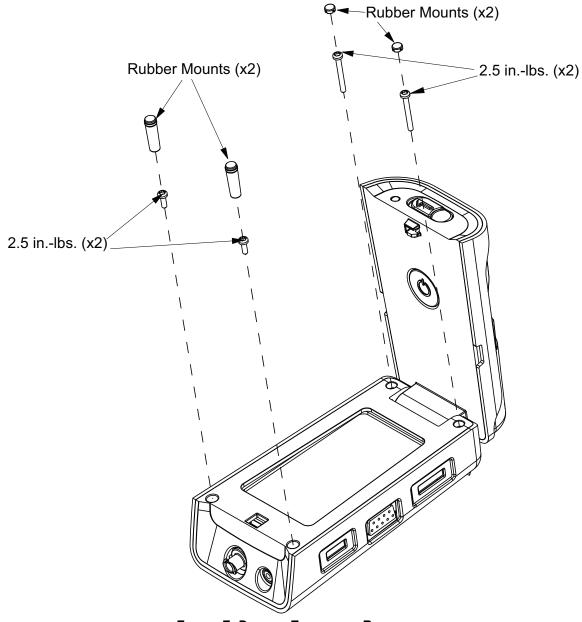


FIGURE F: DISPLAY ENCLOSURE REMOVAL

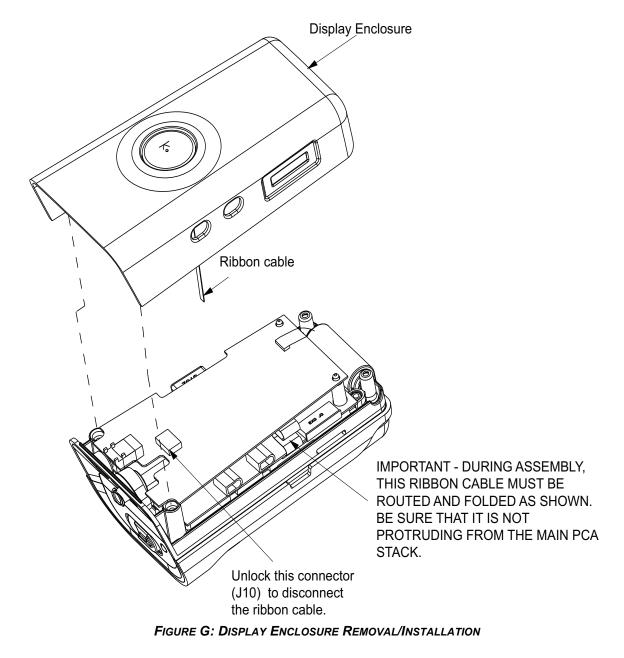


4. Slightly separate the Display Enclosure from the Display Enclosure Cover (part of the Clamshell Assembly).

CAUTION

A Ribbon Cable is connected between the Patient Event Button in the Display Enclosure and the Main PCA Stack. Slightly separate the Display Enclosure from the Clamshell Assembly, then disconnect the Ribbon Cable from the J10 connector on the Digital PCA.

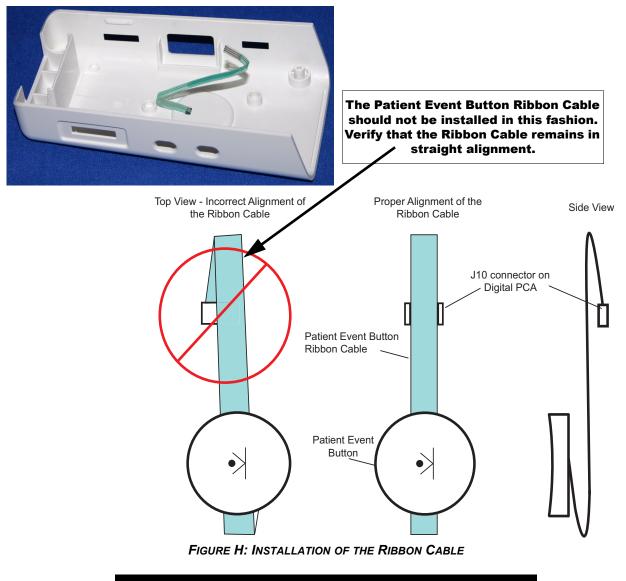
5. Unlock the J10 connector on the Digital PCA (part of the Main PCA Stack) and remove the ribbon cable. The ribbon cable is connected to the patient event button installed in the Display Enclosure.





To install the Display Enclosure:

1. Connect the patient event ribbon cable to the J10 connector located on the Digital PCA (part of the Main PCA stack).



CAUTION

Be sure the Ribbon Cables are routed so as not to be damaged during assembly of the Alice PDx.

- 2. Place the Display Enclosure onto the Clamshell Assembly. Be sure the Display Enclosure snaps onto the Display Enclosure Cover (part of the Clamshell Assembly).
- 3. Secure the Display Enclosure to the Display Enclosure Cover using the four screws removed during the disassembly process.
- 4. Install the Rubber Mounts as shown previously in Figure F.
- 5. Assemble the remainder of the Alice PDx as necessary.



REPLACING THE MAIN PCA STACK

CAUTION

The image shown in Figure I is provided for your convenience and to illustrate the components included with the Main PCA Stack. The Main PCA Stack is assembled and calibrated by Respironics. Do not disassemble the Main PCA Stack. Handle the Main PCA Stack with extreme caution.

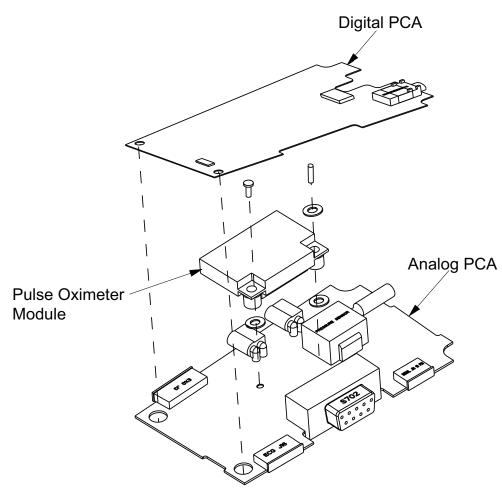


FIGURE I: MAIN PCA STACK COMPONENTS

To remove the Main PCA Stack:

- 1. Remove the Display Enclosure. Refer to page 36 if necessary.
- 2. Disconnect the Flex Cable from the P4 connector located on the Digital PCA.
- 3. Disconnect the LCD Ribbon Cable from the J4 connector located on the under side of the Digital PCA. Not that the LCD Ribbon Cable is locked into the connector.
- 4. Disconnect the Sensor Tube located on the Analog PCA from the Cannula Port.
- 5. Lift the Main PCA Stack out of the Display Holder.



CAUTION

The J4 connector shown in the following illustration is in the unlocked position. It must be in the unlocked position when removing and connecting the LCD Ribbon Cable.



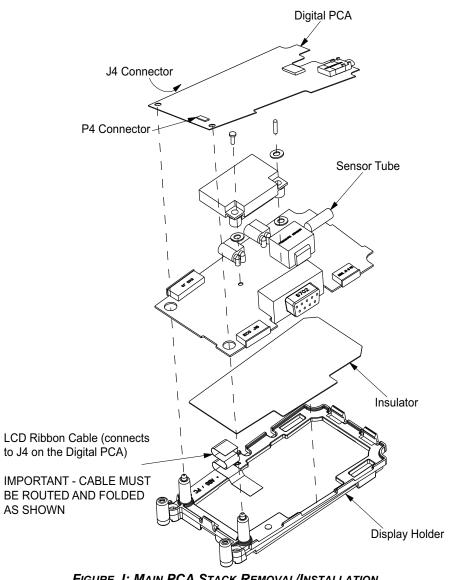


FIGURE J: MAIN PCA STACK REMOVAL/INSTALLATION



To install the Main PCA Stack:

- 1. Connect the Sensor Tube to the Cannula Port.
- 2. Seat the Main PCA Stack in the Display Holder. Be sure the Ribbon Cables are not pinched and are routed for connection in the following steps.
- 3. Connect the LCD Ribbon Cable to the J4 Connector on the Digital PCA.
- 4. Connect the Flex Cable to the P4 Connector on the Digital PCA.
- 5. Assemble the remainder of the Alice PDx as necessary.



REPLACING THE DISPLAY HOLDER AND/OR DISPLAY (LCD)

To remove the Display Holder (w/Display):

- 1. Remove the Display Enclosure. Refer to page 36 if necessary.
- 2. Remove the Main PCA Stack. Refer to page 39 for removal instructions if necessary.
- 3. Lift the Display Holder out of the Display Enclosure Cover.
- 4. Remove the Display from the Display Holder. The Display is equipped with a non-removable Ribbon Cable.

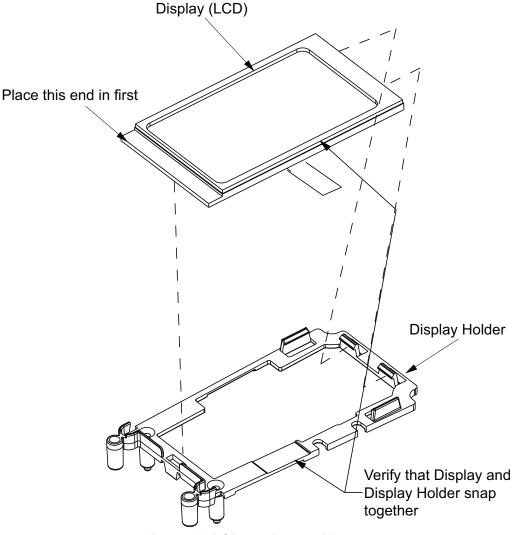
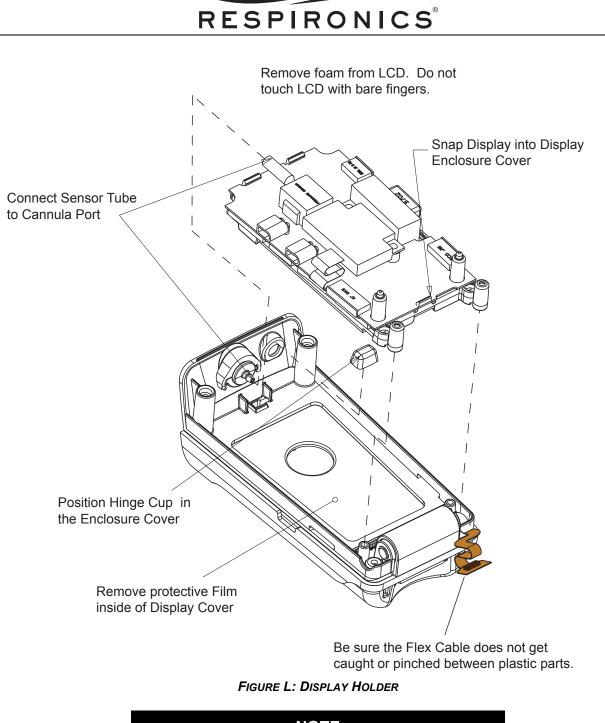


FIGURE K: LCD AND DISPLAY HOLDER

To install the Display Holder with Display (LCD):

- 1. Install the foam on the Display Holder as shown in Figure L.
- 2. Install the Display in the DIsplay Holder as shown above in Figure K.
- 3. Assemble the remainder of the Alice PDx as necessary.



NOTE

The Hinge Cup shown in Figure L replaces a piece of foam that was installed in earlier versions of the Alice PDx.



REPLACING THE CANNULA PORT

To remove the Cannula Port:

- 1. Remove the Display Enclosure. Refer to page 36 if necessary.
- 2. Remove the Main PCA Stack. Refer to page 39 for removal instructions if necessary.
- 3. Unsnap the Cannula Port Cover from the latches on the Cannula Port mount.
- 4. Remove the Cannula Port.

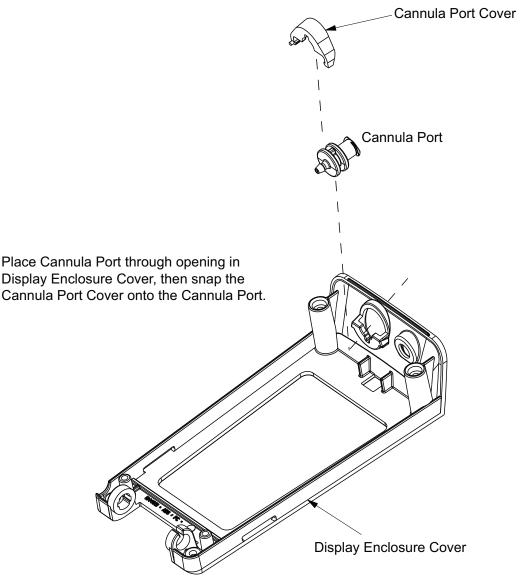


FIGURE M: CANNULA PORT REMOVAL/INSTALL

To install the Cannula Port:

- 1. Place the Cannula Port the opening in the Display Enclosure as shown in Figure M.
- 2. Place the Cannula Port cover over the Cannula Port and snap it into place to secure the Cannula Port.
- 3. Assemble the remainder of the Alice PDx as necessary.

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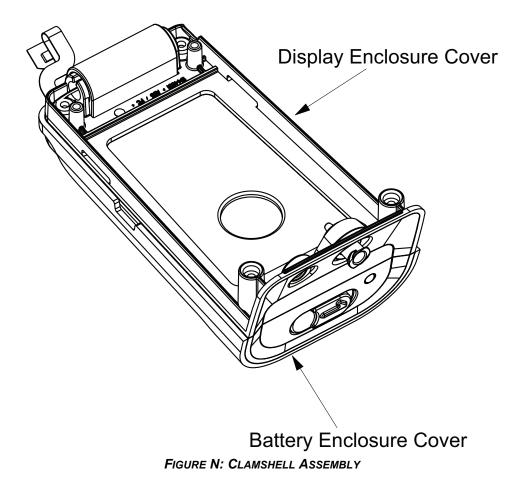


REPLACING THE CLAMSHELL ASSEMBLY

The Clamshell Assembly is pre-assembled and is comprised mainly of the Battery Enclosure Cover and the Display Enclosure Cover.

To remove the Clamshell Assembly:

- 1. Remove the Battery Door and Batteries. Refer to page 32 for removal instructions if necessary.
- 2. Remove the Battery Enclosure. Refer to page 33 for removal instructions if necessary.
- 3. Remove the Battery PCA. Refer to page 34 for removal instructions if necessary.
- 4. Remove the Power Button. Refer to page 35 for removal instructions if necessary.
- 5. Remove the Display Enclosure. Refer to page 36 for removal instructions as necessary.
- 6. Remove the Main PCA Stack. Refer to page 39 for removal instructions as necessary.
- 7. Remove the Display Holder w/Display. Refer to page 42 for removal instructions as necessary.
- 8. Remove the Cannula Port. Refer to page 44 for removal instructions as necessary.



9. Install all components into the Alice PDx and assemble the device as necessary. Refer to the previous Repair/Replace sections of this Manual as necessary.



CLEANING AND MAINTENANCE

This section 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 and holster.
- Then, dry with a clean, dry cloth.



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. Allow to air dry.

LANYARD

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



PERFORMANCE VERIFICATION/POST SERVICE TESTING

This section provides performance verification for the Alice PDx device. Testing shall be performed at periodic intervals commensurate with hospital or homecare provider guidelines for preventative maintenance, and between rentals and patient usage.

REQUIRED TOOLS/EQUIPMENT:

| Tools/Equipment | Part # | Tools/Equipment | Part # |
|--|-------------------------------------|----------------------------------|---------|
| Host PC running Microsoft [®] Windows [®] 2000, XP, or Vista | N/A | Nasal Cannula | P1390 |
| Respironics Alice [®] Sleepware [®] software version 2.7.43 or later | download from my.respironics.com | Pulse Oximeter w/Finger Probe | 936 |
| Three AA batteries | 1055371, 4-pack | Thermistor | P1379 |
| USB to Serial (Communications) Cable | 1040807 | Effort Belts | P1837 |
| ECG Yoke w/Leads | 1040809 (Dom. U.S.) | SD Card | 1053952 |
| | 1040810 (International) | | |
| EXG Yoke w/Leads | 1040808 (Dom. U.S.) | | |
| | 1040815 (International) | | |

PROCEDURE

Perform the following:

- 1. Visually inspect the device, case, display, connections, and buttons for any damage, wear, or other possible defects. (Indicate Pass or Fail on the data sheet.)
- 2. Ensure New, Fully-Charged AA batteries are correctly. (Indicate "Completed" on the data sheet.)
- 3. Ensure that an SD Card is correctly inserted in the SD Card Slot. (Indicate Pass or Fail on the data sheet.)
- 4. Verify that the Alice PDx device is powered ON and that the error indication symbol is not visible. If the error indication symbol is visible and flashing, power OFF the device and replace the Main PCA Stack. Refer to page 39 for replacement procedures. (Indicate Pass or Fail on the data sheet.)





- 5. Verify that Respironics Sleepware[®] is installed on the host computer, if not, proceed with the following software installation instructions:
 - a. You must be logged onto the host computer and have administrative rights (e.g., you can install and remove software, grant permissions to files and folders to other users, etc.)
 - b. Ensure that all folders to be used by specific groups and users have the necessary permissions settings.
 - c. 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.
 - d. Insert the Sleepware CD into the CD drive of your computer and follow the on-screen instructions.
 - e. After installation is complete, create all of the data locations needed (see Sleepware's online help for details).
 - f. 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. Refer to Windows Help and Support for information on security rights. (Indicate "Completed" on the data sheet.)
- 6. Connect the Communications cable between the Alice PDx communications connector and the USB port of host computer.
- 7. Open the Sleepware software and perform *Add Device to Sleepware*.You must add a new Alice PDx device to Sleepware before it can be used:
 - a. Click on the *Configure* button on the Sleepware starter bar and select the *Add/Modify Device* option from the pop-up menu.

| Alice | | Configure |
|-------|-------------------|----------------|
| | Main Menu | 8 ² |
| | Add/Modify Device | |

b. The Add/Modify Device window is displayed.

| /Modify D | ienice | Ł |
|-------------|---------------------------|---|
| | Alice <u>3</u> | |
| a. : | Alice <u>4</u> | |
| 8 | Alice <u>5</u> / Alice LE | |
| | SmartRecorder | |
| | AlicePDx | |
| | Exit | |



- c. Click the *Enable support for Alice PDx* check box and enter a "Friendly" name (a name that is recognizable to you) for the Alice PDx device.
- d. The name you enter will appear on the Sleepware starter bar as a device button.
- e. Click OK to complete the Add Device function.
- f. Ensure all channels are turned ON.
- g. Refer to Sleepware's online help for instructions on how to configure an Alice PDx device for use with Sleepware.
- 8. Upon completion of the *Add Device* function, close Sleepware software and disconnect the communications cable from Alice PDx. (Indicate Pass or Fail on the data sheet.)
- 9. Connect the Thoracic and Abdominal Effort Belts to the Alice PDx device, ensure indicator stops blinking.
- 10. Connect the Nasal Cannula and Oral Thermistor to Alice PDx device, place cannula in position to receive air flow, place the Thermistor between your fingers, and ensure indicator stops blinking.
- 11. Connect the Pulse Oximetry cable with Finger Probe to the Alice PDx device, and ensure indicator stops blinking. (Indicate Pass or Fail on the data sheet.)
- 12. Connect the ECG Yoke with leads to the Alice Pdx Device, and ensure indicator stops blinking.
- 13. Connect the EXG Yoke with leads to the Alice Pdx Device, and ensure indicator stops blinking.

NOTE

For the following tests, allow 20 seconds to pass during the tests to allow for collection of proper data onto SD Card.

- 14. Test the Effort Belts by expanding and contracting the belts. (Indicate Pass or Fail on the data sheet.)
- 15. Test the Nasal Cannula by breathing into or forcing air through the Nasal Openings.(Indicate Pass or Fail on the data sheet.)
- 16. Test the Thermistor by rubbing the end tips to generate heat. (Indicate Pass or Fail on the data sheet.)
- 17. Test the Pulse Ox by placing one index finger in the SpO₂ finger probe. (Indicate Pass or Fail on the data sheet.)
- 18. Test the ECG signal by tapping on all lead wires.
- 19. Touch the lead wires together after the ECG tests to gain ground default signal indication. (Indicate Pass or Fail on the data sheet.)
- 20. Test the EXG signal by tapping on all lead wires. (Indicate Pass or Fail on the data sheet.)
- 21. Touch the lead wires together after the EXG tests to gain ground default signal indication. (Indicate Pass or Fail on the data sheet.)
- 22. Press and hold the Patient Event Button for 4 seconds.
- 23. Power off the Alice PDx device and remove the SD Card.
- 24. Insert the SD Card into a Card Reader. Using Sleepware software, verify the test report indicates signals across tested inputs. (Indicate Pass or Fail on the data sheet.)
- 25. Erase the SD Card. (Indicate "Completed" on the data sheet.)
- 26. Complete the Test Data Sheet.



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TESTING DATA SHEET

Device Model Number: _____

Device Serial Number: _____

RA Number (if applicable): _____

| Test | Step # | Pass | Fail | Completed |
|------------------------|--------------|------|------|-----------|
| Physical Inspection | 1 | | | N/A |
| Install New Batteries | 2 | N/A | N/A | |
| SD Card | 3 | | | N/A |
| Turn ON - No Errors | 4 | | | N/A |
| Sleepware Installation | 5 | N/A | N/A | |
| Communications | 6 | | | N/A |
| Add Device | 7 | | | N/A |
| Effort Belts | 9 & 14 | | | N/A |
| Nasal Cannula | 10 & 15 | | | N/A |
| Thermistor | 10 & 16 | | | N/A |
| Pulse Oximeter | 11 & 17 | | | N/A |
| ECG | 12, 18 & 19 | | | N/A |
| EXG | 13, 20, & 21 | | | N/A |
| Patient event | 22-24 | | | N/A |
| Erase SD Card | 25 | N/A | N/A | |

| Tested By (Print / Sign): | / | Date: | / | / | |
|---------------------------|---|-------|---|---|--|
|---------------------------|---|-------|---|---|--|



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SCHEMATICS

PROPRIETARY STATEMENT

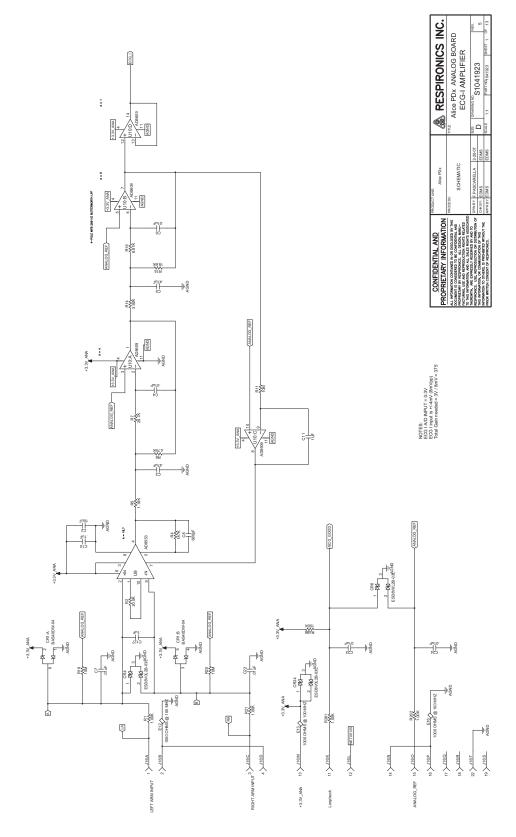
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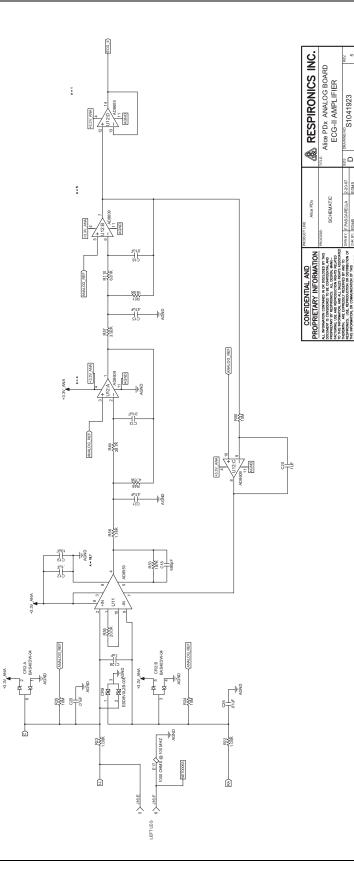
The Schematics are proprietary and confidential. Do not copy the schematics or disclose them to third parties beyond the purpose for which they are intended.

The schematics are intended to satisfy administrative requirements only. They are not intended to be used for component level testing and repair. Any changes of components could effect the reliability of the device, prohibit lot tracking of electronic components, and void warranties. Repairs and testing are supported only at the complete board level.

The schematics are of the revision level in effect at the time this manual was last revised. New revisions may or may not be distributed in the future.

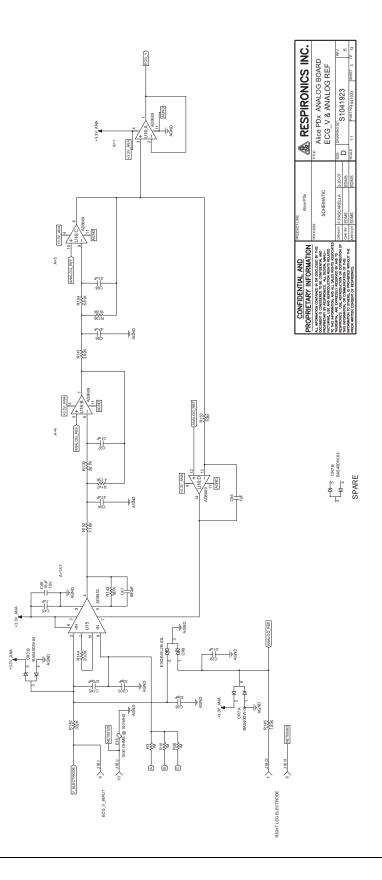


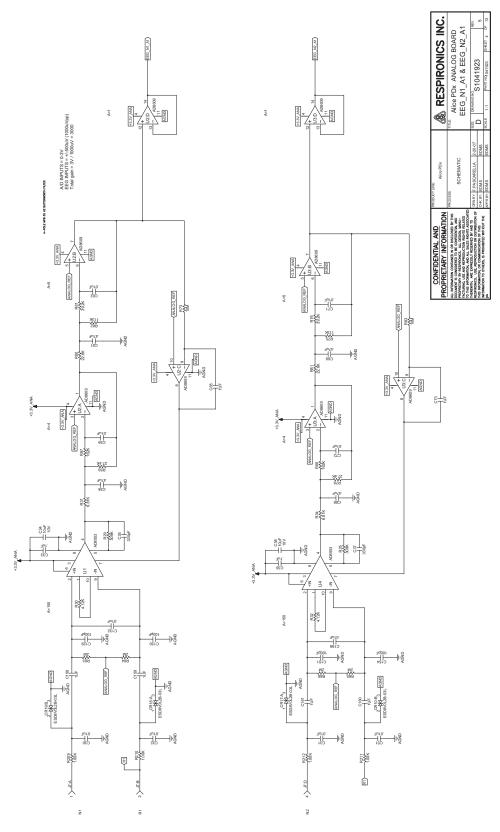




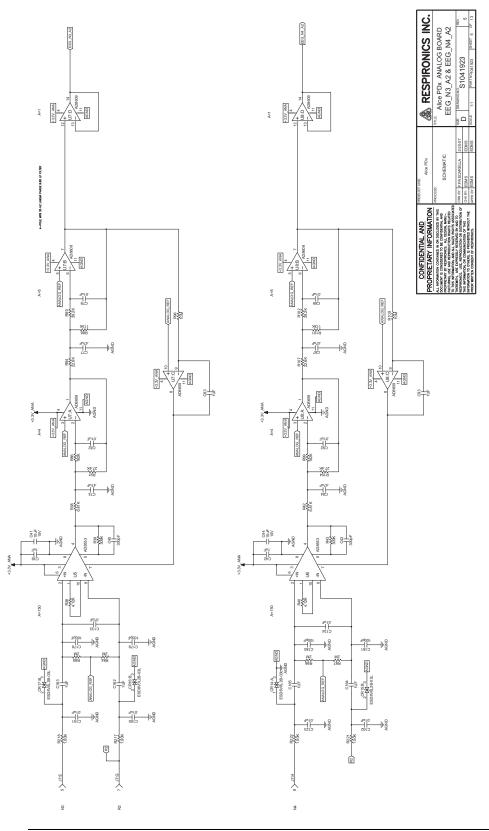
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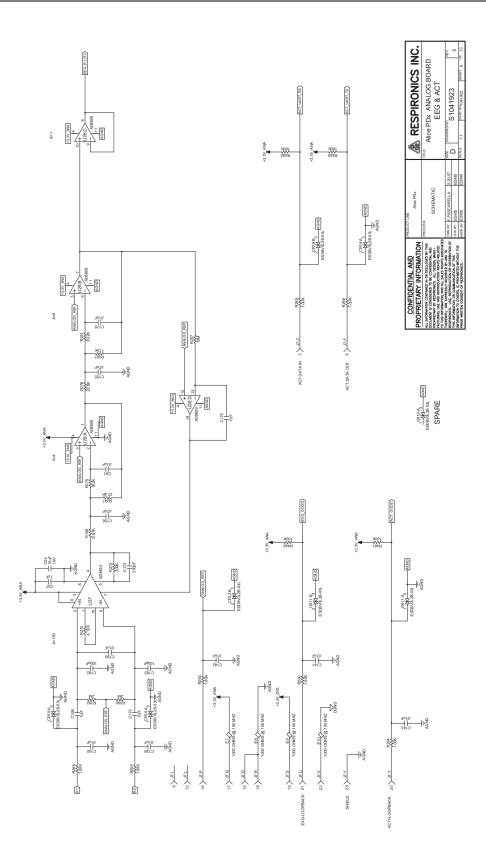




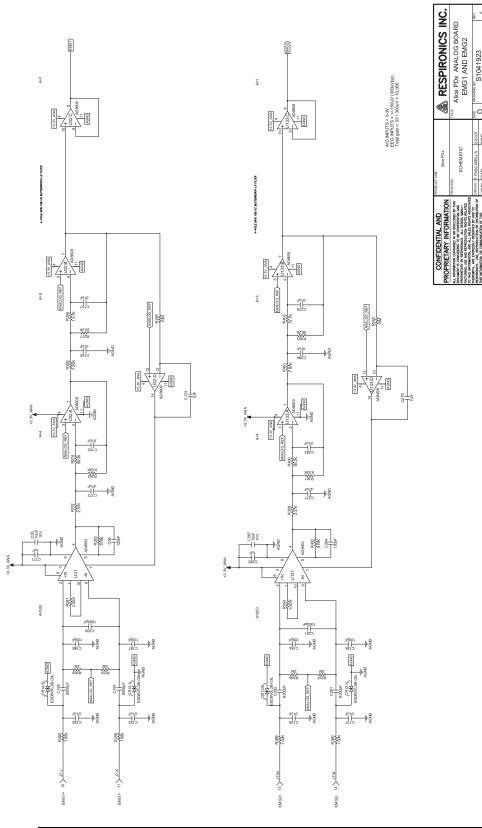


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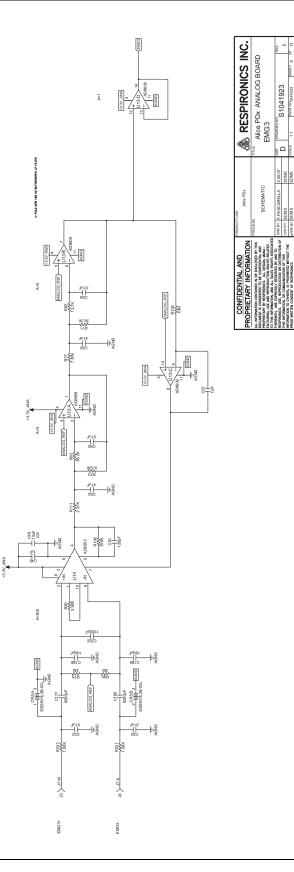




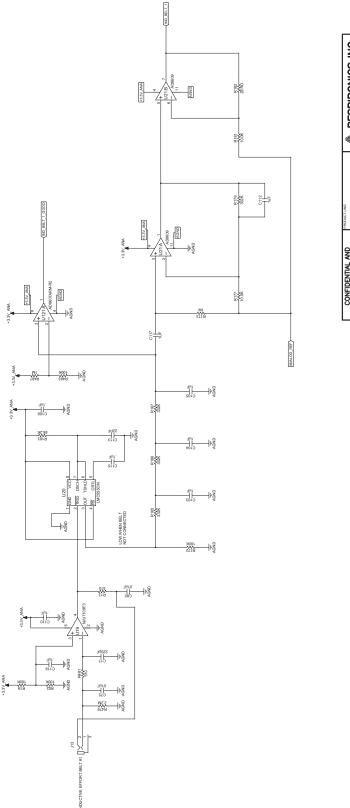


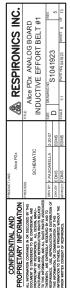
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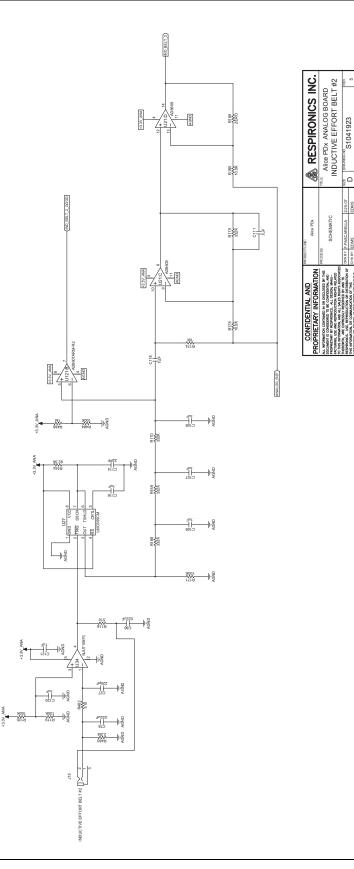
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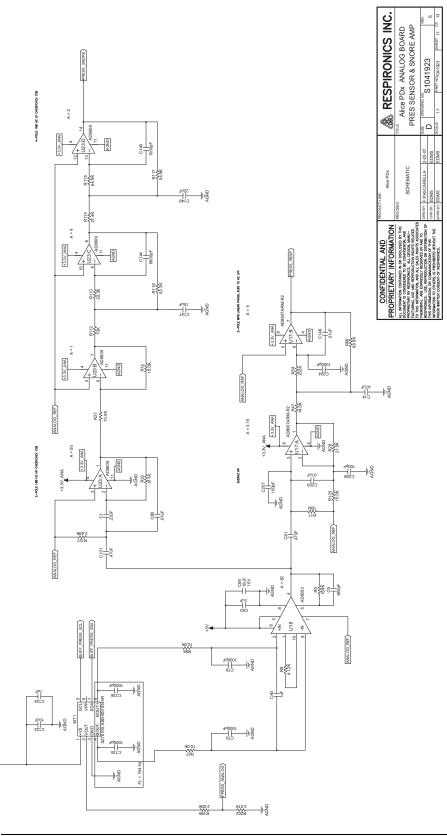


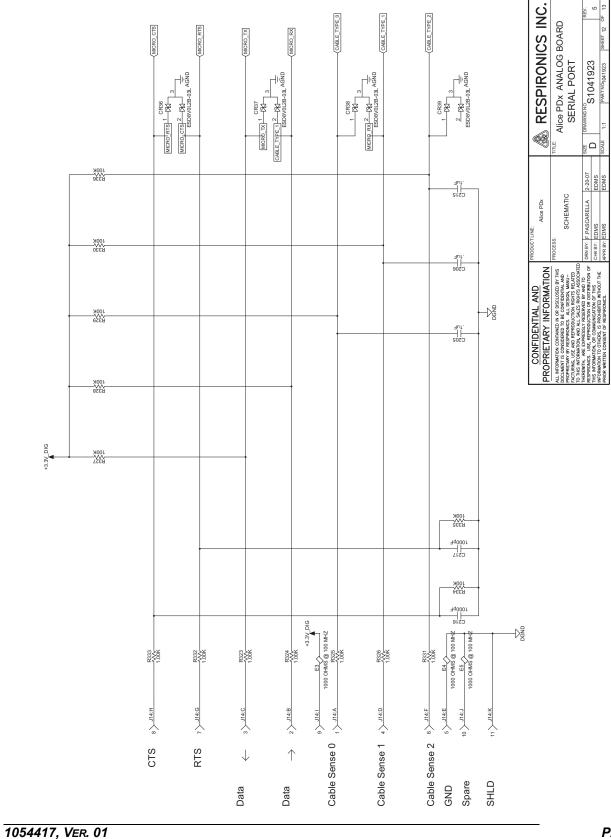








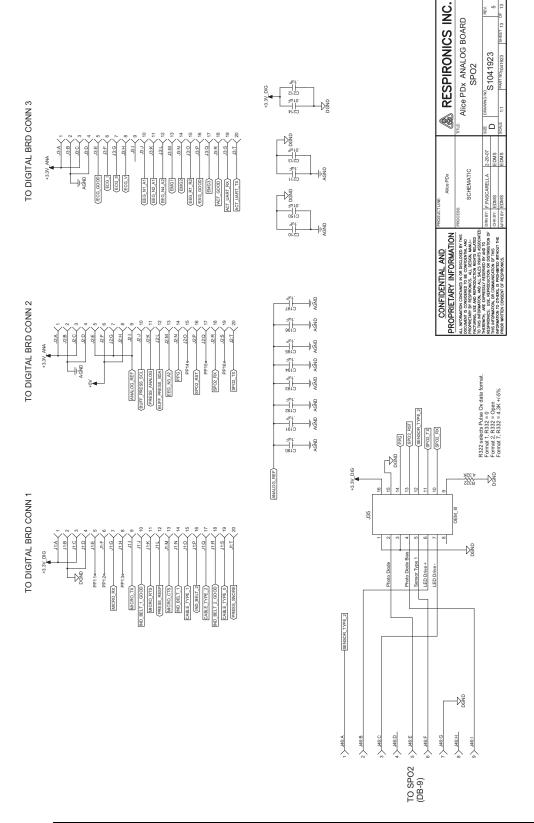




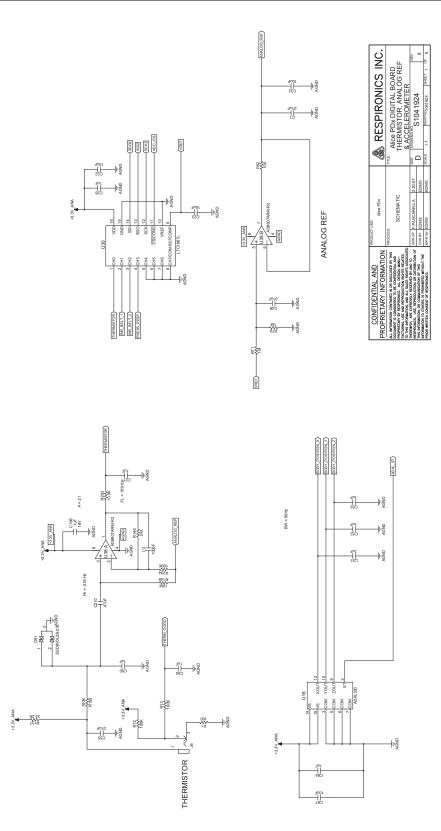
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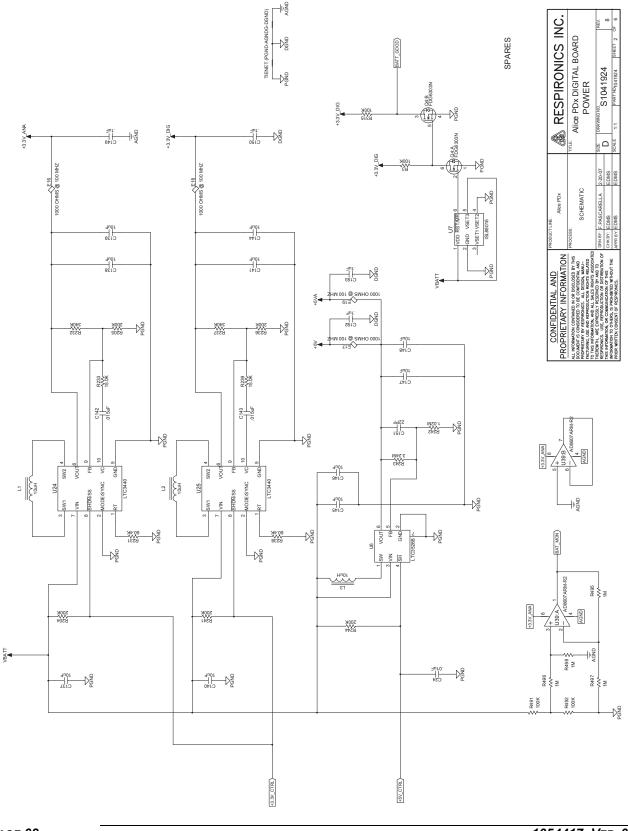




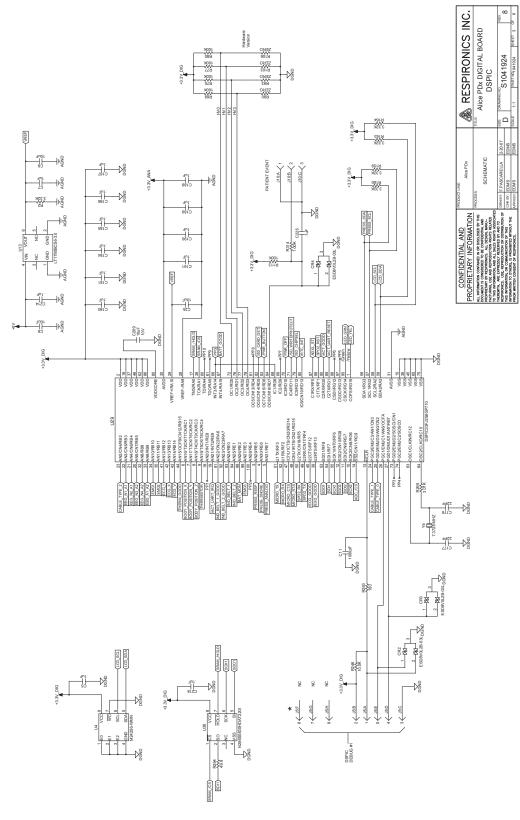
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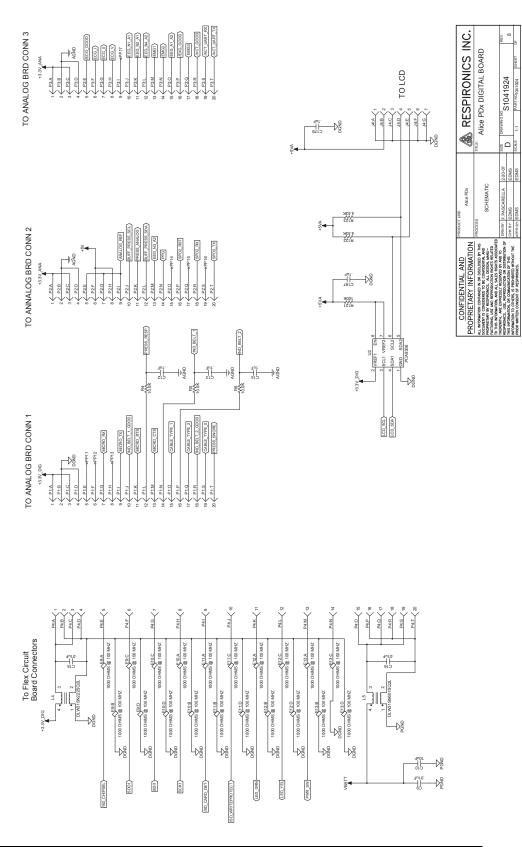


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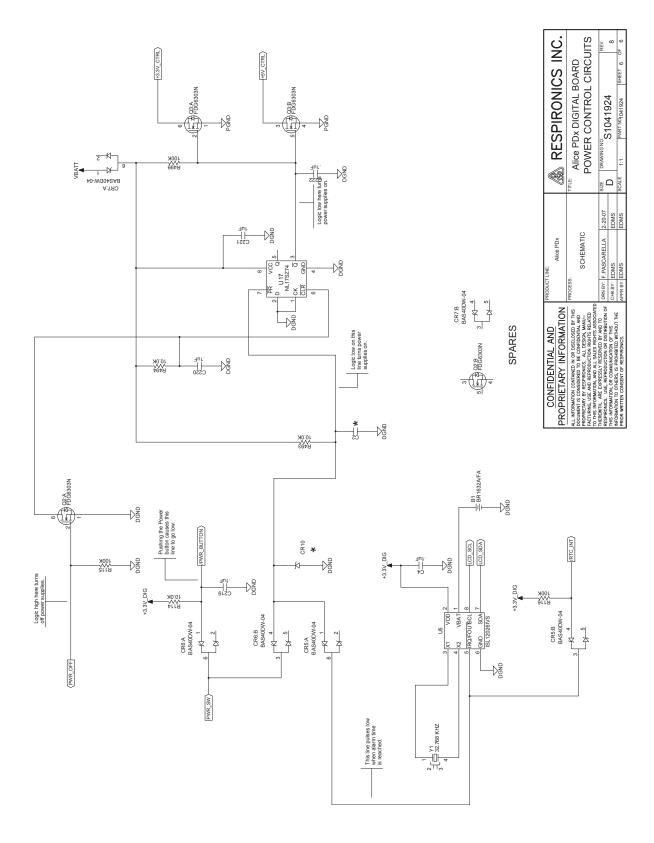


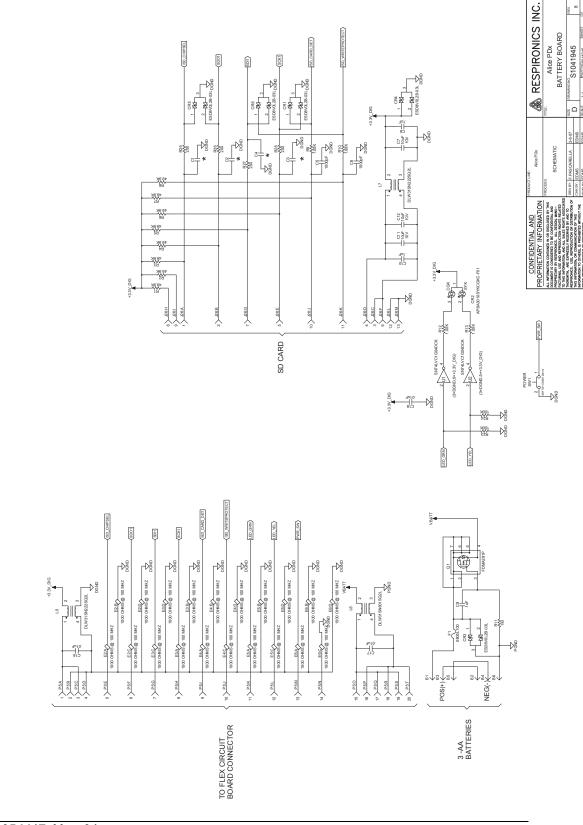
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