BCUTE

Technical Description
for
Digital Pulse Oximeter Module BCUTE-A1

Pre-Release V1.1

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Warnings, Cautions, & Notes

KEYWORD	DEFINITION
WARNING	Tells you about something that could hurt the patient or hurt the operator
CAUTION	Tells you something that could damage the monitor
NOTE	Tells you other important information

Warnings

WARNING! Do not use this device in the presence of flammable anesthetics.

WARNING! Do not use this device in the presence of magnetic resonance imaging (MR or MRI) equipment.

WARNING! This device must be used in conjunction with clinical signs and symptoms. This device is only intended to be an adjunct in patient assessment.

WARNING! Prolonged use or the patient' s condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours.

WARNING! When attaching sensors with Microfoam®[1] tape, do not stretch the tape or attach the tape too tightly. Tape applied too tightly may cause inaccurate readings and blisters on the patient' s skin (lack of skin respiration, not heat, causes the blisters).

WARNING! When connecting this monitor to any instrument, verify proper operation before clinical use. Refer to the instrument' s user manual for full instructions. Accessory equipment connected to the monitor' s data interface must be certified according to the respective IEC standards, i.e., IEC 950 for data processing equipment or IEC 601-1 for electromedical equipment. All combinations of equipment must be in compliance with IEC 601-1-1 systems requirements. Anyone connecting additional equipment to the signal input port or the signal output port configures a medical system, and, therefore, is responsible that the system complies with the requirements of the system standard IEC 601-1-1.

- Cautions

CAUTION! Do not autoclave, ethylene oxide sterilize, or immerse the sensors in liquid.

CAUTION! This device is intended for use by persons trained in professional health care. The operator must be thoroughly familiar with the information in this manual before using the device.

[1] Microfoam® is a registered trademark of the 3M Company

Notes

NOTE! Operation of this device may be adversely affected in the presence of strong electromagnetic sources, such as electrosurgery equipment.

NOTE! Operation of this device may be adversely affected in the presence of computed tomograph (CT) equipment.

NOTE! Use only SpO_2 sensors supplied with, or specifically intended for use with, this device.

NOTE! SpO_2 measurements may be adversely affected in the presence of high ambient light. Shield the sensor area (with a surgical towel, for example) if necessary.

NOTE! Dyes introduced into the bloodstream, such as methylene blue, indocyanine green, indigo carmine, and fluorescein, may adversely affect the accuracy of the SpO_2 reading.

NOTE! Any condition that restricts blood flow, such as use of a blood pressure cuff or extremes in systemic vascular resistance, may cause an inability to determine accurate pulse rate and SpO_2 readings.

NOTE! Remove fingernail polish or false fingernails before applying SpO_2 sensors. Fingernail polish or false fingernails may cause inaccurate SpO_2 readings.

NOTE! SpO_2 averaging is the number of pulse beats over which the SpO_2 value is averaged; pulse averaging is the number of seconds over which the pulse value is averaged.

NOTE! Hazards arising from software errors have been minimized. Hazard analysis was performed to meet EN1441: 1997.

NOTE! Significant levels of dysfunctional hemoglogins, such as carboxyhemoglogin or methhemoglobin, will affect the accuracy of the SpO_2 measurement.

1. Product Description

The PXCO9299-A1 Pulse Oximeter module enables easy OEM integration for fast, reliable %SpO2 and Pulse Rate measurements on any patient, from neonates to adults. Serial communication at 4800 Baud provides the host system with %SpO_2, Pulse Rate, Signal Strength, Bargraph, Plethysmogram, and Status Bits data. The host system can send commands to control the averaging rates, synchronize the Plethysmogram waveform, and request the Oximeter software revision level. The PXCO9299-A1 Pulse Oximeter module has a compact size of 1.1 inches wide by 1.0 inches depth by 0.35 inch high.

2. Theory of Operation

The Oximeter determines %SpO_2 and pulse rate by passing two wavelengths of light, one red (660nm, 2.0mW) and one infrared (905nm, 2.0-2.4mW), through body tissue to a photodetector. During measurement, the signal strength resulting from each light source depends on the color and thickness of the body tissue, the sensor placement, the intensity of the light sources, and the absorption of the arterial and venous blood (including the time varying effects of the pulse) in the body tissues. The Oximeter processes these signals, separating the time invariant parameters (tissue thickness, skin color, light intensity, and venous blood) from the time variant parameters (arterial volume and %SpO_2) to identify the pulse rate and calculate oxygen saturation. Oxygen saturation calculations can be performed because oxygen saturated blood predictably absorbs less red light than oxygen depleted blood.

3. Product Specifications

Data Provided to the Host System

%SpO_2	Range:	0 - 100% Functional SpO_2 (1% increments)
	Accuracy:	± 2 % at 70 – 100 % SpO_2
Pulse Rate	Range:	30 – 254 BPM (1 BPM increments)
	Accuracy:	greater of ±2 BPM or ±2%
Signal Strength		0 - 14
Bargraph		0 - 15
Plethysmogram		0 – 100, auto-gained for highest resolution. 8-bit.
Flags		Pulse Beep No Finger in Sensor Sensor Unplugged Searching for Pulse Searching too long Low Pulse Artifact
Software Revision		Dx.x format transmitted upon request
Serial Communication Logic Levels		TTL voltage levels

Data Provided From the Host System

%SpO_2 Averaging Value	4, 8, or 16 beat averaging (default: 8 beat)
Pulse Rate Averaging Value	8 or 16 second averaging (default: 8 second)
Plethysmogram scale and offset	Synchronized by Host and/or Performed Automatically
Request for software revision	Request for revision level (Dx.x) in a 6-byte format

Power Requirements

Power Supply Input Voltage (typical)	+3.3 ..6 VDC Digital @ 8..11mA electrically isolated

Dimensions

Width	1.1 inches (2.8 cm)
Depth	1.0 inches (2.5 cm)
Height	0.35 inches (0.85 cm)

4. Serial Communications Specifications

The PXCO9299-A1 Pulse Oximeter module communicates with the host computer through a single, high-speed asynchronous serial channel at TTL voltage levels. Data provided to the host includes $\%SpO_2$, Pulse Rate, Signal Strength, Bargraph, Plethysmogram, and Status Bits data. The host can send commands to control the averaging rates, enable/disable the auto synchronization of the Plethysmogram Waveform, request the Oximeter software revision level, setup the Baudrate, setup the sampling-rate.

4.1 Communication Protocol

There are 2 protocols available on the PXCO9299-A1 Pulse Oximeter module which also support the BCI Communications Protocol.

	Baud	**Serial Port Settings Parity - Data – Stop**	**Bytes per Packet**	**Packets Per Sec**
Protocol #1	4800	O-8-1	5	60 (default)
Protocol #2	38400	O-8-1	5	360 selectable

Communication Protocol

Data is transmitted from the Oximeter module with **Protocol #1** to the host at a rate of **60** packages per second. Data is formatted in 5 byte packets. Data packages transmitted from the Oximeter to the host can be synchronized by using bit 7. The communication settings are **4800** Baud, One Start Bit, Eight Data Bits, **Odd** Parity, One Stop Bit (default).

4.2 Serial Communication Notes - Protocol #1 , Protocol #2 ,

Start up averaging is:

%SpO2 - 8 pulses
HR - 8 seconds

- Commands can be sent any time asynchronously with the output data.
- Commands can be sent "back-to-back", except 'E' after 'E' (send revision level). If the Master has not received revision information yet from previous 'E' command, the next 'E' command will be lost. "Revision level" response interrupts normal data stream at any place. It is assumed that 'E' command will be sent once during power up, hence no significant amount of data will be lost.
- When data packets are sent from the Oximeter to the Host, there may be times when there is invalid data (for example, when finger is removed from sensor). Invalid data can be interpreted as:

  invalid Rate = 0xFF
  invalid %SpO2 = 0x7F
  invalid Pleth = 0x7F
  invalid Signal Strength = 0xF

4.2.1 Oximeter Transmitted Data – Protocol

Data is transmitted from the Oximeter module to the Host in 5 byte packets.

Byte	Bit	Description
0	0	Signal Strength 0
	1	Signal Strength 1
	2	Signal Strength 2
	3	Signal Strength 3
	4	1 = searching too long
	5	1 = sensor unplugged
	6	1 = pulse beep
	7	1 (sync. bit)
1	0	Plethysmogram 0
	1	Plethysmogram 1
	2	Plethysmogram 2
	3	Plethysmogram 3
	4	Plethysmogram 4
	5	Plethysmogram 5
	6	Plethysmogram 6
	7	0 (sync. bit)
2	0	Bargraph 0
	1	Bargraph 1
	2	Bargraph 2
	3	Bargraph 3
	4	1 = no finger in sensor or sensor unplugged
	5	1 = searching for pulse
	6	Rate 7 (see byte 4)
	7	0 (sync. bit)

Byte	Bit	Description
3	0	Rate 0
	1	Rate 1
	2	Rate 2
	3	Rate 3
	4	Rate 4
	5	Rate 5
	6	Rate 6
	7	0 (sync. bit)
4	0	%SpO2 0
	1	%SpO2 1
	2	%SpO2 2
	3	%SpO2 3
	4	%SpO2 4
	5	%SpO2 5
	6	%SpO2 6
	7	0 (sync. bit)

Revision Level Packet Protocol

Byte 0: 0x80 (128)
Byte 1: 0xFF (255)
Byte 2: 0x44 (‘V’)
Byte 3: One’s value in ASCII, i.e., if revision 1.1, 0x31
Byte 4: Decimal value in ASCII

4.2.3 Oximeter Received Data – Protocol

The host system can send single character commands to the Oximeter to change the averaging values, synchronize the Plethysmogram scale and offset, and force the Oximeter to send the software revision level.

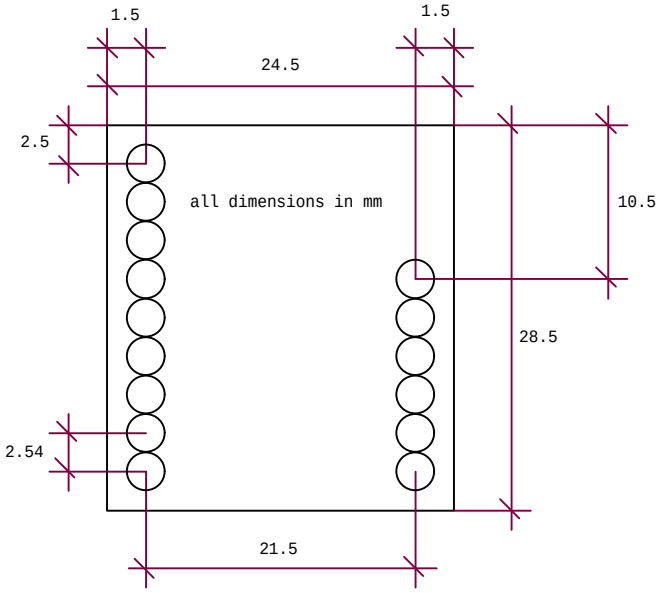
ASCII	Description
A	Synchronizes the Plethysmogram scale and offset to the next sample. Subsequent offset adjustments will also occur when the Plethysmogram value exceeds the range 0 - 99. The Plethysmogram scale and offset are automatically adjusted every 256 samples.
B	Sets %SpO2 to 4-beat average and pulse rate to an 8-second average.
C	Sets %SpO2 to 8-beat average and pulse rate to an 8-second average (default).
D	Sets %SpO2 to 16-beat average and pulse rate to a 16-second average.
E	Forces Oximeter to send software revision level (Dx.x) in a 5-byte format: Byte 1: 80H Byte 2: FFH Byte 3: V for digital (ASCII) Byte 4: Ones digit (ASCII) Byte 5: Tenths digit (ASCII)
F	Switch onboard 8-Bit – DAC on/off.

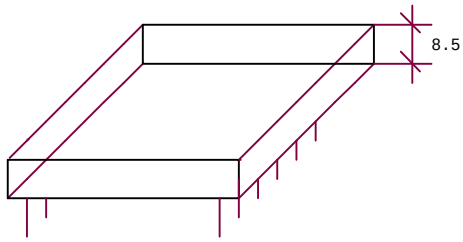
5. Pin Description J1-Power and Communication Connector

J1 Pin	Description
1	PULS-LED (optional)
2	for 4800BD connect to +3.3V ***OR*** for 38400BD connect to GND
3	RESET (low active, optional)
4	n.c. (only for in-circuit-test)
5	DAC – Analog-OUT
6	TxD (TTL Level)
7	RxD (TTL Level)
8	GND
9	+VCC 3.3 V

J2-Oximeter Sensor Connector

J2 Pin	Sensor Cable	DB9 Pin
1	R-Led	2
2	IR-Led	3
3	CAL (for future use)	1
4	GND	7/8
5	Opto	5
6	+V Opto	9





8. Checking Pulse Oximeter Performance

Pulse Oximeters do not require user calibration. To check the function of the device, an optional Oximeter Simulator is available as an accessory (Index 2PFE, Smart-Sat). The simulator attaches to the Oximeter in place of the sensor or patient cable. It provides a known %SpO2 and pulse rate signal to the Oximeter, allowing the Oximeter's performance to be checked.
Follow the instructions included with the Oximeter Simulator.

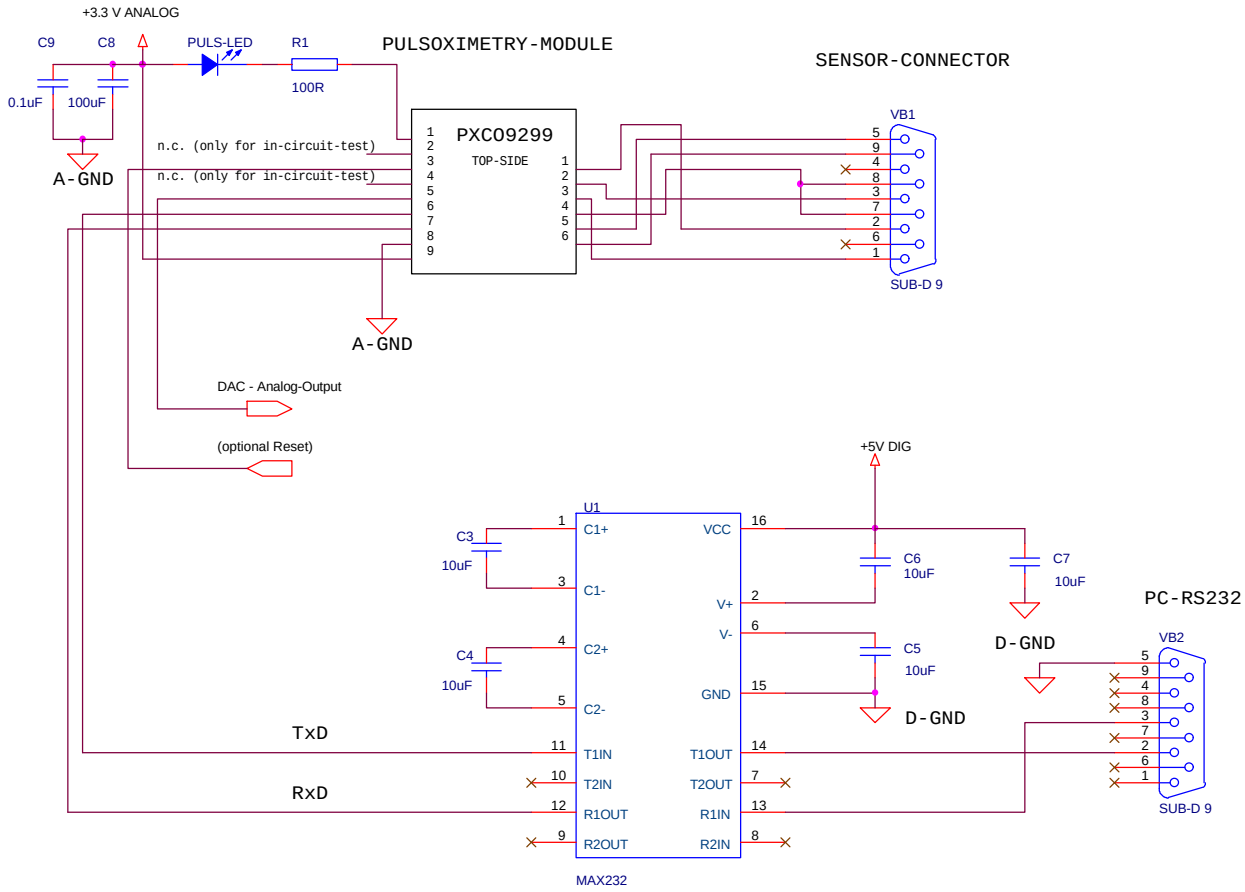
9. Demonstration Software

The PC software is for demonstration purposes only. The intent is to allow the OEM customer to quickly become familiar with the operation of the Oximeter module**. This software is NOT to be used in any product for sale. This circuit shown below, for interface to a PC for demonstration purposes, is for evaluation only and is to be used with a %SPO2 simulator. Do not connect directly to a patient without proper patient isolation.**

	Demonstration Software
PXCO9299	PXCO9299.EXE

The PXCO9299-A1 Oximeter module can be connected to your PC through a custom power/communication interface board.

A **sample schematic which could be used for the PC interface** is shown below.


+3.3 V ANALOG
C9
C8
PULS-LED
R1
PULSOXIMETRY-MODULE
SENSOR-CONNECTOR
0.1uF
100uF
100R
A-GND
n.c. (only for in-circuit-test)
n.c. (only for in-circuit-test)
PXC09299
TOP-SIDE
VB1
SUB-D 9
A-GND
DAC - Analog-Output
(optional Reset)
+5V DIG
U1
C3
10uF
C4
10uF
C1+
C1-
C2+
C2-
VCC
V+
V-
GND
C6
10uF
C5
10uF
C7
10uF
D-GND
D-GND
PC-RS232
VB2
SUB-D 9
TxD
RxD
T1IN
T2IN
R1OUT
R2OUT
T1OUT
T2OUT
R1IN
R2IN
MAX232