Integrated Pulse Oximetry Device
Specifications

1.	Oxygen Saturation Range	0 to 100%	
2.	Pulse Rate Range	18 to 300 pulses per minute	
3.	Measurement Wavelengths	Red - 660 Nanometers Infrared - 925 Nanometers	
4.	Accuracy		
	SpO_2 (70-100%) (±1 SD)♦	No Motion	
		- Adults	±2 digits
		Motion	
		- Adults	±3 digits
		Low Perfusion	
		- Adults	±3 digits
	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
5.	Temperature		
	a) Operating	0° C to +50° C	
	b) Non Operating	-30° C to +50° C	
6.	Humidity		
	a) Operating	10 to 90% Non Condensing	
	b) Non Operating	10 to 95% Non Condensing	
7.	Power Draw	60 mW - typical operating	
8.	Voltage Input	2 to 6 volts dc operating Note: Sensor is not isolated from input voltage	
9.	Output Digital Signals	0 - 5 volts (nominally)	
10.	Patient Isolation	Meets IEC 60601-1 Dielectric Withstand	
11.	Leakage Current	Not applicable	
12.	Dimensions	1.26" x 1.25" x 2" (32 x 32 x 51mm)	
13.	Weight	100g (including 1m cable and connector)	
14.	Ruggedness immersion		
	a) Shock	Per IEC 68-2-27	
	b) Vibration	Mil-standard 810C, method 514-2	

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

INPUTS:
Red Wire = V+ (2-6VDC, 60mW typical)
Black Wire = Ground
Cable Shield = Ground (Both Black wire and cable shield must be attached to ground on the host device)
Note: Sensor is not isolated from input voltage.

OUTPUTS:
Green Wire = Serial Output (TTL)
Blue Wire = Serial Output (RS-232)

FORMATTING OPTIONS:

PART #	MODEL #	SERIAL DATA FORMAT #	LENGTH	CONNECTOR
3830-001	3211	#1	1m	No
3830-101	3211	#1	1m	Yes
3831-001	3212	#2	1m	No
3831-101	3212	#2	1m	Yes

SERIAL DATA FORMAT #1:

1) Serial format — 9600, n, 8, 1
2) Rate — Sends 3 bytes of data once a second.
3) Data

1st byte = **Status**

BIT 7 = **ALWAYS SET TO "1"**
BIT 6 = SENSOR DISCONNECTED, SET IF TRUE
BIT 5 = OUT OF TRACK, SET IF TRUE
BIT 4 = LOW PERFUSION, SET IF TRUE
BIT 3 = MARGINAL PERFUSION, SET IF TRUE
BIT 2 = BAD PULSE, SET IF TRUE
BIT 1 = HEART RATE BIT 8
BIT 0 = HEART RATE BIT 7

2nd byte = **Heart Rate** (511 = bad data) BIT "7" IS ALWAYS SET TO "0".
HEART RATE DATA = BITS 0 - 6
PLUS BITS 0 & 1 OF THE STATUS BYTE TO PROVIDE 9 BITS OF RESOLUTION.

3rd byte = **SpO2** (127 = bad data)

SERIAL DATA FORMAT #2:

1) Serial format — 9600, n, 8, 1
2) Rate — Sends 5 bytes of data 75 times a second.
3) Data

a. HR value bits 7&8 (128-511), 511 = bad data	1 byte	3 times a second
b. HR value bits 0-6 (0-127)	1 byte	3 times a second
c. SpO2 value 0 - 100	1 byte	3 times a second
d. Firmware revision level	1 byte	3 times a second
e. Status byte 128 - 255	1 byte	75 times a second

Bit 0 frame Sync, set for 1 of 25, clear for 2-25 of 25
Bit 1 green perfusion, set if true only during pulse
Bit 2 red perfusion, set if true only during pulse
Bit 3 sensor alarm, set if true
Bit 4 out of track, set if true
Bit 5 bad pulse, set if true
Bit 6 sensor disconnected, set if true
Bit 7 always set

Note: bits 1 & 2 are set for yellow perfusion.

f. Plethysmographic pulse value 0 - 254	1 byte	75 times a second
g. Sync character (01)	1 byte	75 times a second
h. Checksum = byte 1 + byte 2 + byte 3 + byte 4	1 byte	75 times a second

Extended Averaging Data

i. E-HR value bits 7&8 (128-511), 511 = bad data	1 byte	3 times a second
j. E-HR value bits 0-6 (0-127)	1 byte	3 times a second
k. E-SpO2 value 0 - 100	1 byte	3 times a second

Non-Slew Limited with Standard Averaging

l. SpO2 Slew value 0 - 100, 127 = bad data	1 byte	3 times a second

Beat to Beat Value (No Averaging or Slew Limiting)

m. SpO2 B-B value 0 - 100, 127 = bad data	1 byte	3 times a second

Display Data

SpO2 Display Value with Standard Averaging

n. 0-11, 127 = bad data	1 byte	3 times a second

E-SpO2-D Display Value with Extended Averaging

o. 0-100, 127 = bad data	1 byte	3 times a second

HR-D-MSB Display Value with Standard Averaging

p.HR Value bits 7&8, 511 = bad data	1 byte	3 times a second

HR-D-LSB Display Value with Standard Averaging

q. HR Value bits (0-6) (0-127)	1 byte	3 times a second

E-HR-D-MSB Display Value with Extended Averaging

r. HR Value bits 7&8, 511 = bad data	1 byte	3 times a second

E-HR-D-LSB Display Value with Extended Averaging

s. HR Value Bits 0-6 (0-127)	1 byte	3 times a second

Data is sent in the following format

Hz	BYTE					Hz	BYTE					Hz	BYTE				
1/75	1	2	3	4	5	1/75	1	2	3	4	5	1/75	1	2	3	4	5
1	01	STATUS	PLETH	HR MSB	CHK	26	01	STATUS	PLETH	HR MSB	CHK	51	01	STATUS	PLETH	HR MSB	CHK
2	01	STATUS	PLETH	HR LSB	CHK	27	01	STATUS	PLETH	HR LSB	CHK	52	01	STATUS	PLETH	HR LSB	CHK
3	01	STATUS	PLETH	SpO2	CHK	28	01	STATUS	PLETH	SpO2	CHK	53	01	STATUS	PLETH	SPO2	CHK
4	01	STATUS	PLETH	REV	CHK	29	01	STATUS	PLETH	REV	CHK	54	01	STATUS	PLETH	REV	CHK
5	01	STATUS	PLETH	*	CHK	30	01	STATUS	PLETH	*	CHK	55	01	STATUS	PLETH	*	CHK
6	01	STATUS	PLETH	*	CHK	31	01	STATUS	PLETH	*	CHK	56	01	STATUS	PLETH	*	CHK
7	01	STATUS	PLETH	*	CHK	32	01	STATUS	PLETH	*	CHK	57	01	STATUS	PLETH	*	CHK
8	01	STATUS	PLETH	*	CHK	33	01	STATUS	PLETH	*	CHK	58	01	STATUS	PLETH	*	CHK
9	01	STATUS	PLETH	*SpO2-D*	CHK	34	01	STATUS	PLETH	*SpO2-D*	CHK	59	01	STATUS	PLETH	*SpO2-D*	CHK
10	01	STATUS	PLETH	*SpO2 Slew*	CHK	35	01	STATUS	PLETH	*SpO2 Slew*	CHK	60	01	STATUS	PLETH	*SpO2 Slew*	CHK
11	01	STATUS	PLETH	*SpO2 B-B*	CHK	36	01	STATUS	PLETH	*SpO2 B-B*	CHK	61	01	STATUS	PLETH	*SpO2 B-B*	CHK
12	01	STATUS	PLETH	*	CHK	37	01	STATUS	PLETH	*	CHK	62	01	STATUS	PLETH	*	CHK
13	01	STATUS	PLETH	*	CHK	38	01	STATUS	PLETH	*	CHK	63	01	STATUS	PLETH	*	CHK
14	01	STATUS	PLETH	*E-HR MSB*	CHK	39	01	STATUS	PLETH	*E-HR MSB*	CHK	64	01	STATUS	PLETH	*E-HR MSB*	CHK
15	01	STATUS	PLETH	*E-HR LSB*	CHK	40	01	STATUS	PLETH	*E-HR LSB*	CHK	65	01	STATUS	PLETH	*E-HR LSB*	CHK
16	01	STATUS	PLETH	*E-SpO2*	CHK	41	01	STATUS	PLETH	*E-SpO2*	CHK	66	01	STATUS	PLETH	*E-SpO2*	CHK
17	01	STATUS	PLETH	*E-SpO2-D*	CHK	42	01	STATUS	PLETH	*E-SpO2-D*	CHK	67	01	STATUS	PLETH	*E-SpO2-D*	CHK
18	01	STATUS	PLETH	*	CHK	43	01	STATUS	PLETH	*	CHK	68	01	STATUS	PLETH	*	CHK
19	01	STATUS	PLETH	*	CHK	44	01	STATUS	PLETH	*	CHK	69	01	STATUS	PLETH	*	CHK
20	01	STATUS	PLETH	*HR-D MSB*	CHK	45	01	STATUS	PLETH	*HR-D MSB*	CHK	70	01	STATUS	PLETH	*HR-D MSB*	CHK
21	01	STATUS	PLETH	*HR-D LSB*	CHK	46	01	STATUS	PLETH	*HR-D LSB*	CHK	71	01	STATUS	PLETH	*HR-D LSB*	CHK
22	01	STATUS	PLETH	*E-HR-D MSB*	CHK	47	01	STATUS	PLETH	*E-HR-D MSB*	CHK	72	01	STATUS	PLETH	*E-HR-D MSB*	CHK
23	01	STATUS	PLETH	*E-HR-D LSB*	CHK	48	01	STATUS	PLETH	*E-HR-D LSB*	CHK	73	01	STATUS	PLETH	*E-HR-D LSB*	CHK
24	01	STATUS	PLETH	*	CHK	49	01	STATUS	PLETH	*	CHK	74	01	STATUS	PLETH	*	CHK
25	01	STATUS	PLETH	*	CHK	50	01	STATUS	PLETH	*	CHK	75	01	STATUS	PLETH	*	CHK

* Undefined

IPod Precautions for Use

Contraindications

- Do not use the Ipod in an MRI environment.

Warnings

- Explosion Hazard: Do not use the Ipod in an explosive atmosphere or in the presence of flammable anesthetics or gases.
- Loss of monitoring can result if any objects hinder the pulse measurement. Ensure that no blood flow restrictors (e.g., blood pressure cuff) hinder pulse measurements.
- As with all medical equipment, carefully route cables and connections to reduce the possibility of entanglement or strangulation.
- This device does not meet defibrillation-proof requirement per IEC 60601-1: 1990, clause 17.h.
- This device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed carefully to verify normal operation.
- Operation of this device below the amplitude of 0.5% modulation may cause inaccurate results.

Cautions

- This pulse oximetry system is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin. Significant levels of dysfunctional hemoglobin, such as methemoglobin, might affect the accuracy of the measurement.
- The Ipod has motion tolerant software that minimizes the likelihood of motion artifact being misinterpreted as good pulse quality. In some circumstances, however, the Ipod may still interpret motion as good pulse quality. This covers all available outputs.
- Inspect the sensor application site at least every 4 hours to ensure correct sensor alignment and skin integrity. Patient sensitivity may vary due to medical status or skin condition.
- This equipment complies with International Standard EN 60601-1-2:2001 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of interference due to close proximity or strength of a source might disrupt the device's performance. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed and put into service according to the EMC information specified in this document.
- This device has not been tested for immunity to electromagnetic disturbances.
- Portable and mobile RF communications equipment can affect medical electrical equipment.
- Use of the pulse quality indicator (provided with all output formats) is recommended to aid in detecting a patient's perfusion level.

For more information about required safety and regulatory requirements for medical devices, refer to EN865 and IEC 60601-1.

Intended Use

The Ipod is intended to provide medical device manufacturers with a small, low-power device that can be easily integrated into a host device. The module measures functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate (BPM) for adult, pediatric, and neonatal patients. When mated with a medical device manufacturer's host system, the Ipod may be used in any environment where pulse oximetry measurements are made.

Manufacturer's Declaration

Refer to the following table for specific information regarding this device's compliance to IEC Standard 60601-1-2.

Table 1: Electromagnetic Emissions

Emissions Test	**Compliance**	**Electromagnetic Environment— Guidance**
This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.		
RF Emissions CISPR 11	Group 1	This 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	Class B	This device is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	N/A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	N/A	

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