Dolphin Medical
An OSI SYSTEMS Company

INTEGRATION MANUAL

OEM-701 MODULE

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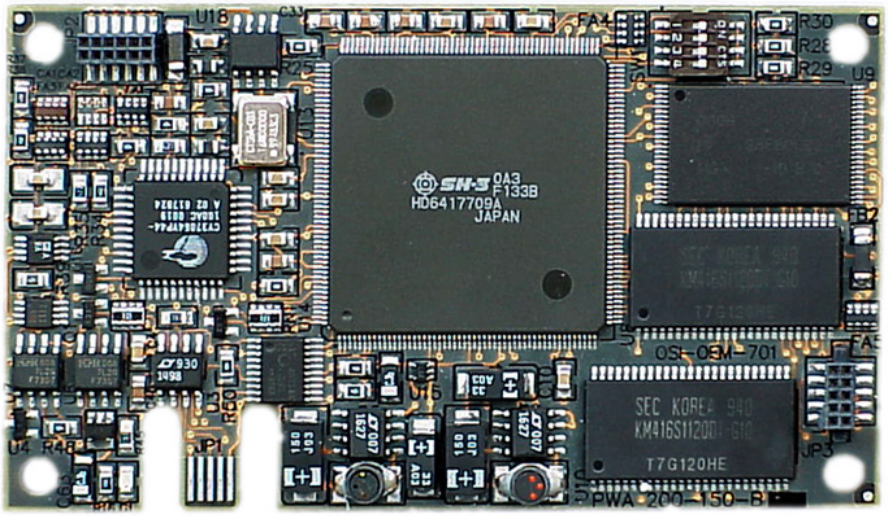
http://www.dolphinmedical.com



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1.0 Product Description

The OEM-701 Module uses digital signal processing with the Fast Fourier Transform (FFT) to identify and reject motion artifacts associated with patient motion. FFT analysis results in improved performance with low-perfusion patients, and reduces the frequency of nuisance alarms. The module measures SpO2, Pulse Rate, and Temperature on adult, pediatric and neonatal patients.

1.1 Digital Signal Processing Plus Digital Optical Sensor

The OEM-701 Module uses an advanced digital signal-processing (DSP) engine capable of discerning pulsatile waveforms in the presence of motion, making the module ideal for use in demanding clinical environments. Additionally, Dolphin ONE Oximetry Sensors return digital information to the OEM-701 Module, instead of the more traditional low-level analog signals, thereby eliminating corruption of the sensor waveform by external electrical noise sources.

1.2 Physical

The OEM-701 Module is a multi-layer double-sided PCB populated with surface-mount components.

- Size: 3.50” X 2.00” (88.9mm X 50.8mm)
- Power consumption: 0.60W (normal)
- Voltage: +5V +/- 5%
- Current: 120mA (normal)

1.3 Communications

The OEM-701 Module communicates with the host computer through a single, asynchronous serial channel at TTL voltage levels. Data provided to the host includes:

- SpO2%
- Pulse Rate
- Bar graph intensity proportional to AC/DC ratio
- Graphical display of Photo-Plethysmogram
- Sensor Status Information
- Temperature (thermistor sensor)

This protocol does not require any commands from the host. However, the protocol does make provision for commands sent from the Host. These commands can enable special features and give the host platform additional control over the OEM-701 operation; also, the command protocol can be used to instruct the OEM-701 to transmit additional parameters in the serial data. In certain cases, Dolphin Medical may redesign this protocol or match an existing host protocol to ease integration of the OEM-701 Module.

The transmitted “frame” of data is defined on the next page. This data is transmitted at 19200bps, 8 data bits, no parity, 1 stop bit (19200, 8-N-1). No hardware or software flow control is implemented in this protocol. The frames are transmitted 27.5 times per second.

The Standard Host Protocol is defined in Tables 1 and 2. Table 1 describes the data being sent from the OEM-701 to the host; Table 2 is a description of the command frame sent from the host to the OEM-701 module.

NOTE: Example C source code for protocol handling is available from Dolphin Medical on request.

Table 1: Standard Host Protocol (Data)

BYTE NUMBER	FIELD SIZE (Bytes)	FIELD DESCRIPTION
0	1	**STX** Start of frame character – 03h Binary code to indicate the first byte of the frame.
1	1	**FRAME SIZE** This field indicates the total size of the transmitted frame including STX and EOF. This allows the reserved diagnostics data area to be dynamically expanded in the future as software changes. Currently the diagnostics field requires 42 bytes for the reserved data area.
2	1	**FRAME COUNT** Binary number indicating the current frame number; this number increments from 00h to 1Ah, then rolls over to 00h; all parameters contained in frame data are sent once per second; hosts may use this count to recover from UART overruns, framing errors, checksum errors or other events which cause frames to be lost.
3-4	2	**FRAME DATA** The Frame Count field determines the contents of these two frame data bytes. The contents for each stage are listed below:
		Frame Count = 0 %SpO2 (0.0 % to 100.0 %) Byte 3: Integral part of %SpO2 (0% to 100%) Byte 4: Fractional part of %SpO2, in tenths of a percent (0 % to .9 %) The host may choose not to use the second byte (tenths of a percent), but should round the integral number if not using the fractional part. This field is set to 0 when SpO2 cannot be resolved.
		Frame Count = 1 Pulse **Standard Mode (30 to 240 bpm):** Byte 3: Integral part of Pulse Rate (30 to 240 bpm) Byte 4: Fractional part of Pulse Rate, in tenths of a bpm (.0 to .9) **Veterinary Mode (20 to 450 bpm):** Byte 3: Bits (7:0) = Bits(7:0) of integral part of Pulse Rate Byte 4: Bit 7 = Bit 8 of integral part of Pulse Rate Byte 4: Bits (3:0) = Fractional part of Pulse Rate, in tenths of a bpm (.0 to .9) The host may choose not to use the second byte (tenths of a percent)), but should round the integral number if not using the fractional part. This field is set to 0 when pulse rate cannot be resolved.
		Frame Count = 2 For Future Use
		Frame Count = 3 Signal Strength (0 to 100), Signal Quality (0 to 10) Signal Strength indicates the measured perfusion. Signal Strength values of 5 or less indicate low perfusion. Signal Quality indicates the measured signal to noise of the waveform. Signal Quality values of 5 or less indicate a low quality signal. Byte 3: Signal Quality Value (0 to 10) >> OEM versions 7.40 and later Byte 4: Signal Strength Value (0 to 100) This field is set to 0 when perfusion or signal quality cannot be measured.

		Frame Count = 4 Sensor And Measurement Status Bit field indicating sensor status and SpO2 measurement status. This field should be used as the basis of displaying status and error messages. The bits are defined as follows: Byte 3: Sensor Status Bit #0 = Sensor connected 0 = Sensor connected 1 = No sensor connected Bit #1 = Sensor off patient 0 = Sensor on patient 1 = Sensor off patient Bit #2 = Defective sensor 0 = Sensor OK 1 = Sensor defective Bit #3 = Low perfusion 0 = Normal perfusion 1 = Low perfusion detected Bit #4 = Pulse search 0 = Pulse found 1 = Pulse search in progress Bit #5 = Too much ambient light 0 = Ambient light normal 1 = Too much ambient light Bit #6 = Insufficient light 0 = Normal signal levels detected 1 = Insufficient signal Bit #7 = Interference detected >> OEM versions 7.40 and later 0 = Normal signal 1 = Interference detected (excessive ambient light, pulse out of range, etc.) Byte 4: Sensor Type 0 = 2 LED Sensor 1 = 4 LED Sensor
		Frame Count = 5 System Status Byte 3: Status Byte #1 1 = Power On Self Test Diagnostics Passed Others = Power On Self Test Diagnostics FATAL ERROR Code Byte 4: Status Byte #2 1 = Power On Self Test Diagnostics Passed Others = Power On Self Test Diagnostics FATAL ERROR Code
		Frame Count = 6 Software Revision Level The single-digit Major Revision number and the 3-digit Minor Revision number are encoded into this frame. They are in the format *M.mmm*, where *M* = Major and *m* = Minor. Byte 3: Major Revision Level and first Minor digit (packed BCD format). Byte 4: Minor Revision Level, digits 2 and 3 (packed BCD format) Example: Byte 3 = 64h, Byte 4 = 12h, Version Number = 6.412
		Frame Count = 7 Operating Status Byte 3: Patient Type 0 = Adult Mode 1 = Neonatal Mode 2 = Pediatric Mode 3 = Veterinary Mode Byte 4: Sensitivity Level 0 = Normal Sensitivity 1 = High Sensitivity
		Frame Count = 20 Temperature Celsius (0.00° to 60.00°) Byte 3: Integer part of temperature (0° to 59°) Byte 4: Fractional part of temperature, in hundredths of a degree (.00° to .99°) The host may choose not to use the second byte, but should round the integer number if not using the fractional part.

		NOTE: If BOTH the Celsius and Fahrenheit values are 0.00, the host should conclude that the sensor is not connected.
		Frame Count = 21 Temperature Fahrenheit (32.0° to 138.9°) Byte 3: Integer part of temperature (32° to 138°) Byte 4: Fractional part of temperature, in hundredths of a degree (.00° to .99°) The host may choose not to use the second byte, but should round the integer number if not using the fractional part. NOTE: If BOTH the Celsius and Fahrenheit values are 0.00, the host should conclude that the sensor is not connected.
5	1	**BAR GRAPH INTENSITY AND PULSE BEEP INDICATOR** Binary number used by the host to display a visual indication of the pulse. This feature is most useful with host systems that do not graphically display the photo-plethysmogram waveform. As perfusion of the patient decreases, the peak value of this field decreases. The data in this field is dependent on thermistor mode. **Thermistor Operation Disabled:** Bits 6:0 = Bar graph intensity (0 to 100) Bit 7 = Pulse beep indicator **Thermistor Operation Enabled:** Bits 3:0 = Bar graph intensity (0 to 10) Bit 6 = Reserved Bit 7 = Pulse beep indicator
6-7	2	**PHOTO-PLETHYSMOGRAM WAVEFORM DATA** 16-bit Binary value of the auto-scaled plethysmogram waveform Possible values range from 0000h to FFFFh. Byte 6: Least Significant Byte of the 16-bit value. Byte 7: Most Significant Byte of the 16-bit value. Hosts may choose to only employ the Most Significant Byte if their method of display will not benefit from the added resolution of the full 16-bit value.
8-(Frame Size-3)		**RESERVED DATA** The reserved data field. This size of this field is dynamic and can be determined by the Frame Size field.
Frame Size-2	1	**LINEAR CHECKSUM** This checksum is applied from the FRAME SIZE byte to the last RESERVED DATA field byte (bytes 1 to FRAME SIZE -3), inclusive.
Frame Size-1	1	**END OF FRAME** End of frame character - 04h Binary code to indicate the last byte of the frame

Table 2: Standard Host Protocol (Command)

BYTE NUMBER	FIELD SIZE (Bytes)	FIELD DESCRIPTION
0	1	**STX** Start of frame character – 03h Binary code to indicate the first byte of the frame.
1	1	**FRAME SIZE** This field indicates the total size of the transmitted frame including STX and EOF
2	1	**FRAME TYPE** Binary number indicating the type of frame.
3	1	**FRAME DATA** The Frame Type field determines the contents of this byte. The contents for each type are listed below: Frame Type = 0 Set Operating Mode 0 = Adult operating mode (default) 1 = Neonatal operating mode 2 = Pediatric operating mode 3 = Veterinary operating mode Frame Type = 2 Set Sensitivity Level 0 = Normal sensitivity (default) 1 = High sensitivity Frame Type = 6 Thermistor Operation (Temperature) 0 = Disable (default) 1 = Enable The operating mode parameter should be stored in non-volatile memory by the host and should be transmitted to the OEM-701 Module after reset/power up. This initial parameter transmission should only occur after the host has detected a valid serial stream from the OEM-701 Module to ensure the OEM-701 Module is ready to receive commands.
4	1	**LINEAR CHECKSUM** This checksum is applied from the FRAME SIZE byte to the last FRAME DATA field byte (bytes 1 to FRAME SIZE -3), inclusive.
5	1	**END OF FRAME** End of frame character - 04h Binary code to indicate the last byte of the frame

2.0 Switch Settings

The module has a 4-posiiton DIP switch, labeled "SW1". These switches are used to enable or select features on the module, such as serial protocols. *These switch selections have not yet been defined and should all be set to off.*

3.0 Connections

The OEM-701 Module provides two connectors for use by the host system (See Figure 3). The Host Interface Connector (JP3) contains the communications, power, and reset signals for the module. The Sensor Interface Connector (JP2) contains the signals used to drive and read the Dolphin ONE Oximetry Sensors.

A third connector, JP1, is used for production purposes; it has no useful purpose for the host system and should be left unconnected.

3.1 JP2 – Sensor Interface Connector

Connector JP2 carries the signals to and from the digital sensor. It is a 0.05" 12-circuit (2x6) socket. The connector part number is "Samtec SFMC-106-T2-D". See Figure 3 for placement of pin #1. Table 3 defines the connector signals.

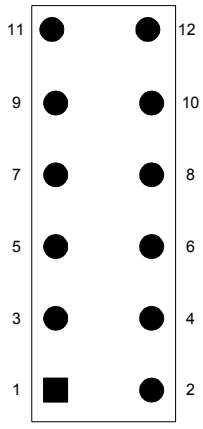


Figure 1.

Table 3: Sensor Interface Connector Definition

Pin Number	Direction (relative to the OEM-701)	Description
1	In	Detector output; 50% duty cycle square wave, TTL levels, 0 to 750kHz
2	In	ROWA – LED control signal
3		GND
4	In	ROWB – LED control signal
5		Reserved
6	Out	COLA – LED control signal
7	In/Out	Select line (for Sensor Type)
8	Out	COLB – LED control signal
9	Out	Thermistor
10		Power (+5V)
11		Reserved
12		Reserved

The thermistor connection allows a standard 400-series thermistor sensor to be connected to the OEM-701. The temperature is determined and transmitted as described in the communications protocol. See Section 12 of this document for a schematic description of the electrical connections. For information regarding thermistor sensors, contact Dolphin Medical.

3.2 JP3 – Host Interface Connector

Connector JP3 contains the power supply, reset signal, and communications channels for the OEM 701 Module. . It is a 0.05" 10-circuit (2x5) socket. The connector part number is either "Amp 104652-1" or "Samtec SFM-105-02-S-D-A". See Figure 3 for placement of pin #1. Table 4 defines the connector signals.

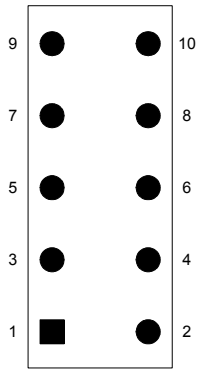


Figure 2.

Table 4: Host Interface Connector Definition

Pin Number	Direction (relative to the OEM-701)	Description
1		Power +5V
2		GND
3		Not Used
4		GND
5		Not Used
6		GND
7	In	RESET – TTL – Low to reset Dolphin ONE Pulse Oximetry OEM-701 Module SH3 micro-processor
8		Not Used
9	In	RX – Serial Receive (TTL)
10	Out	TX - Serial Transmit (TTL)

3.3 Connector Suggestions

The following are two sets of parts that can be used as mating connectors to the OEM-701. The only difference between the two sets of parts is the total resulting stack height.

- For a total stack height of **7.5mm**:
  Power/Comm Connector: *Samtec TFM-105-12-S-D*
  Sensor Connector: *Samtec FTSH-106-04-L-DV*

- For a total stack height of **5.8mm**:
  Sensor Connector: *Samtec FTS-106-01-L-DV*
  Power/Comm Connector: *Samtec TFM-105-02-S-D*

- For reference, the connectors used on the OEM-701 are:
  Sensor Connector : *Samtec SFMC-106-T2-D*
  Power/Comm Connector : *Samtec SFM-105-02-2-D-A*

4.0 Dimensions

Figure 3, below, contains the board perimeter measurements, connector locations, and the location of the holes for connection to the host system. Table 5 gives additional mechanical details of the board.

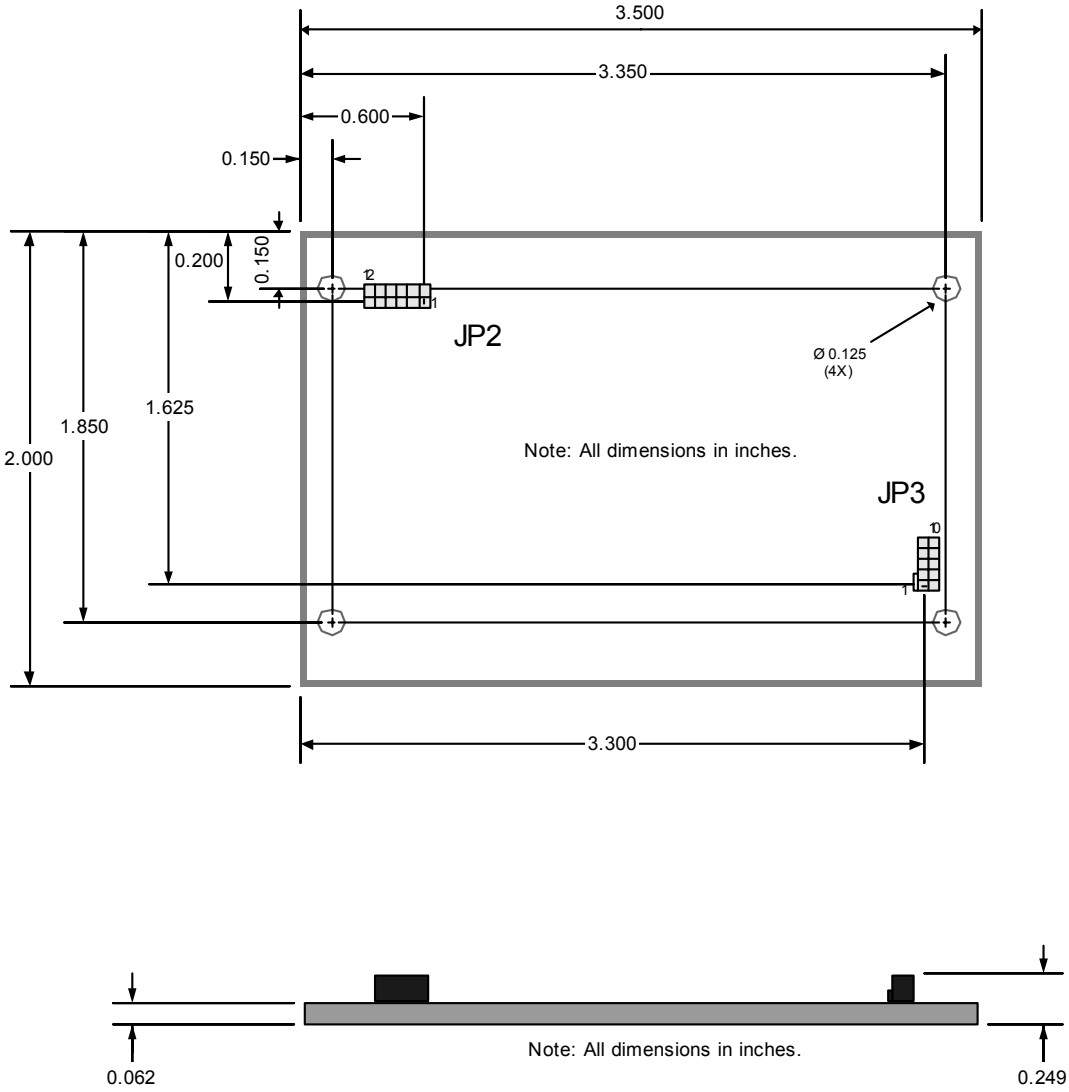


Figure 3: Board Dimensions.

Table 5: OEM-701 Mechanical Details

Measurement	Inches	Millimeters
Total Width	2.00”	50.8 mm
Total Depth	3.50”	88.9 mm
Board (PCB) Thickness	0.062”	1.574 mm
Height Above Board	0.187”	4.749 mm
Height Below Board	0.05”	1.27mm
Mounting Holes (diameter)	0.125”	3.175 mm

5.0 Measurements

5.1 Range

SpO_2 (functional)	0 % – 100 %
Pulse Rate (bpm)	30 – 240 bpm
Perfusion	0.02 % – 20 %
Temperature (°C)	0.0°C – 60.0°C
Temperature (°F)	32.0°F – 138.9°F

Where Perfusion % $= (AC/DC)_{905}$ X 100

5.2 Resolution

SpO_2 (functional)	0.1%
Pulse Rate (bpm)	0.1 bpm
Temperature (°C or °F)	0.01°

5.3 Accuracy

Accuracy of SpO2, Pulse Rate and Temperature are given in Table 6.

Table 6: SpO2 and Pulse Rate Accuracy

Parameter	Patient Type	Signal Condition	Range	Accuracy
SpO_2 (functional)	Adult or Pediatric	No Motion and Normal Perfusion	70 – 100	± 2 %
			0 – 69	Unspecified
	Neonate*	No Motion and Normal Perfusion	70 – 100	± 3.5 %
			0 – 69	Unspecified
Pulse Rate (bpm)	Adult, Pediatric, or Neonate	No Motion and Normal Perfusion	30 – 240	± 3 bpm
SpO_2 (functional)	Adult or Pediatric	Motion or Low Perfusion < 0.2 %	70 – 100	± 3 %
			0 – 69	Unspecified
Pulse Rate (bpm)	Adult or Pediatric	Motion or Low Perfusion < 0.2 %	30 – 240	± 5 bpm
Temperature (°C)			32.0 – 42.0	0.1°
			0.0 – 31.9, 42.1 – 60.0	0.2°
Temperature (°F)			89.6° – 107.6°	0.2°
			32.0° – 89.5° 107.7° – 138.9°	0.4°

* This specification is based upon SpO2 testing on adult subjects under normal perfusion with an accuracy of ± 2.5%. Literature predicts an increase in accuracy range of ± 1% for neonates accounts for the effect of fetal hemoglobin in neonatal blood.

6.0 Power Requirements

The power requirements for the OEM-701 oximetry board are defined in Table 7. The Average Power is meant for battery gauging only. The OEM-701 performs bursts of processing which can cause peaks in supply current up to twice the average current rating. Additionally, the initial inrush current of the OEM-701 will exceed the capability of most 1-Watt DC-DC converters. Therefore, Dolphin Medical advises the use of a 2-Watt power supply. See Section 15 for suggestions in OEM-701 support circuitry.

Table 7: Power Requirements

Parameter	Min	Typical	Max
Voltage Supply	+4.75V	+5V	+5.25V
Current (operating)		120 mA	
Supply Ripple	---	---	100mV p-p

7.0 Environmental Requirements

Operating Temperature	-5˚ to 45˚C
Operating Relative Humidity	5% - 95% non-condensing
Operating Pressure	503 hPa – 1059 hPa
Storage Temperature	-20 to 60˚C
Storage Relative Humidity	5% - 95% non-condensing
Storage Pressure	503 hPa – 1059 hPa

8.0 Patient Isolation Requirements

As part of the system design, the host system must provide electrical isolation for all connections to the module to meet requirements of UL2601, IEC 601-1 and all other applicable electrical safety specifications. The OEM-701 Module, except for clear silicon RTV insulation over the optical sensor, provides no patient isolation. This clear silicon RTV optical sensor insulation must not be considered when evaluating patient isolation, since the optical sensor may become wet or damaged if misused.

This device, or a functional equivalent, has been successfully tested to satisfy FDA (510k) and European (CE) requirements when integrated into a properly designed host platform.

9.0 Patents

The OEM-701 Module is covered by the following US Patents:

- US Patent 5,575,284
- US Patent 5,830,137
- US Patent 5,368,025
- US Patent 5,217,012

- US Patent 5,429,129
- US Patent 6,011,985

Note: This list does not include patents pending approval.

10.0 Service

The OEM-701 Module requires no routine service. The OEM-701 Module is guaranteed for one (1) year. In the unlikely event of board malfunction, a replacement can be obtained via express shipping overnight. Shipping the malfunctioning unit back to Dolphin Medical for internal engineering analysis and troubleshooting can obtain credit to the customer's account for the full price of the OEM-701 module.

11.0 Sensors and Accessories

An assortment of Dolphin ONE Oximetry Sensors for pulse oximetry applications is available directly from Dolphin Medical, Inc. Additionally, Dolphin Medical will work with OEM customers to make sensors available for private labeling. This OEM module supports standard 2-LED oximetry sensors as well as Dolphin Medical's high-performance 4-LED sensors. For more information about the 4-LED sensor function, please call.

Note: Refer to the Directions for Use accompanying Dolphin ONE Oximetry Sensors and Extension Cables for complete instructions about sensor selection and use, and use and maintenance of patient cables.

Sensor	REF	Use	Patient type
DOLPHIN ONE Adult Sensor	520	Single Use	Adults and Pediatrics > 30 kg
DOLPHIN ONE Neonatal Sensor	560	Single Use	Neonates and Pediatrics ≤ 30 kg
DOLPHIN ONE Adult Finger Clip	210	Reusable	Adults and Pediatrics > 30 kg
8 ft Extension Cable	110	Reusable	All

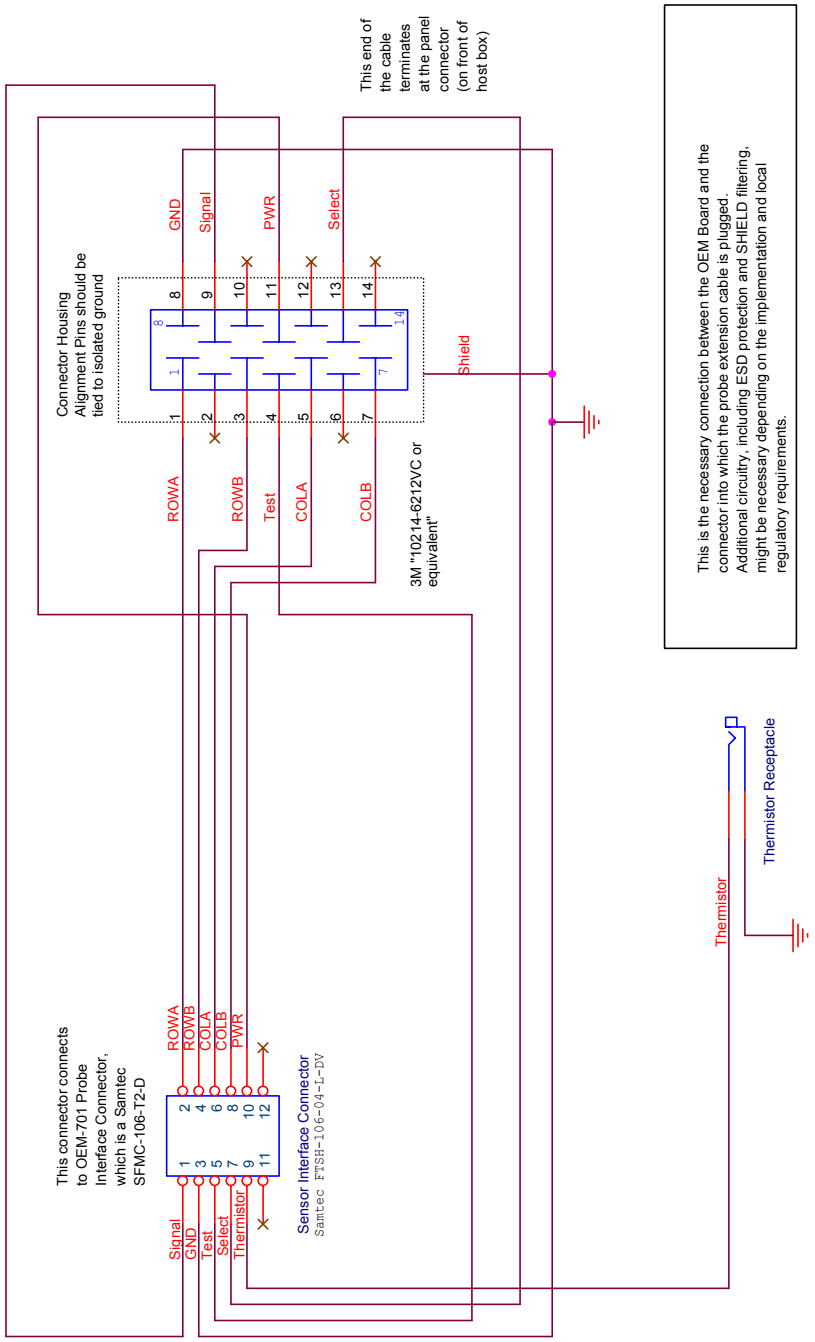
OTHER ACCESSORIES

Accessory	REF
Integration Manual, English	LT-010701
Service and Maintenance Manual	LT-030701

12.0 Suggested Sensor Circuitry Layout for Host Platform

This schematic below, Figure 5, describes the necessary connection between the OEM-701 Sensor Interface Connector (JP2) and the Dolphin Medical Extension Cable Connector, as well as the connection to a thermistor sensor.

Figure 5: Suggested Sensor Layout



13.0 Guidance for use of Sensitivity Level and Operating Mode

The command protocol for the OEM-701 allows the host to set the Sensitivity Level and Operating Mode of the oximetry board. Refer to the Communications section of this document for the exact format of the commands.

The following guidance should aid the host integrator in using these features.

13.1 Sensitivity Level

For routine use, the Normal Sensitivity should be selected. The High Sensitivity selection may be used when the patient is very poorly perfused and should only be enabled manually.

In the High Sensitivity mode, the OEM-701 will detect and measure the smallest pulsatile signals; however, because of this, the High Sensitivity mode is more likely to be affected by external interference (motion artifact, light noise). Additionally, the ability to detect an asystole event is greatly diminished. This High Sensitivity mode should only be used when the patient is being closely monitored.

The low-perfusion specifications of this oximetry module were measured with the module in the Normal Sensitivity level. Because the module performs very well in this mode, the host integrator may choose not to allow the user to change the sensitivity level.

The default (start-up) sensitivity level is “Normal”.

13.2 Operating Mode

The Dolphin ONE DSP algorithms are tuned to the patient type. This setting is automatically made when a sensor is connected. However, the setting can be changed by issuing the appropriate command to the oximetry module.

Use this “override” feature when the sensor type and the patient type do not match. For example, if a “neonatal” sensor (i.e., the DD560) is used on an adult patient, Adult Mode may be selected.

Changing the operating mode will not affect the accuracy of the Pulse Rate or SpO2%. The operating mode aids the oximetry module in resolving the correct pulse rate in the presence of extreme motion artifacts. Therefore, although it is not necessary to change the operating mode for different patient types, doing so may result in better “noise rejection” performance when the sensor type does not match the patient type. The host integrator may choose not to allow this “override” feature to be available to the user.

14.0 Thermistor Sensor Design Information

The OEM-701 board has thermistor-based temperature capabilities. The following are recommendations on how to design or purchase the appropriate temperature sensor to be used with the OEM-701. Refer to the Communications section of this document for the exact format of the commands to enable the temperature feature.

14.1 Thermistor Sensor

The OEM-701 board is designed and has been calibrated for use with a YSI 400 series compatible thermistor. This is a common and regularly used thermistor for sensing patient temperature in the medical field. There are many different types of YSI 400 series medical thermistor sensors available (Skin, nasal, rectal, Etc.). Dolphin Medical does not recommend any one type to another. This is usually a choice based on the type of monitor in which the OEM-701 will be incorporated.

If you choose to design a thermistor sensor, the following list of manufacturers supply a selection of different thermistors:

- Thermometrics Inc. (www.thermometrics.com)
- Alpha Sensors Inc. (www.alphasensors.com)
- Yellow Springs (www.ysi.com)

There are many medical manufactures that currently use YSI 400 series sensors in their medical monitors. The following list of manufacturers use and sell finished YSI 400 series sensors:

- Heska (www.heska.com) (look at Cat #6076 temperature kit)
- ViaMed (www.viamed.co.uk)
- Criticare Systems, Inc. (www.csiusa.com)
- Minnesota Wire & Cable Co. (www.mwccmme.com/mnwire/ysipage.html)
- EFS Electronique (www.efs.fr)
- Genesee Biomedical, Inc. (www.geneseebiomedical.com)

A few things that must be considered if you are designing or purchasing a finished thermistor sensor is the connector end on the thermistor and the extension cable. Most YSI 400 sensors have a 2 pin Molex connector. Most manufacturers make their own interface cable from the 2 pin Molex to a phono plug going into their monitor.

The OEM-701 has been calibrated to the stated specifications in section 5 using a YSI 400 thermistor. If the sensor in use exceeds these specifications, the temperature accuracy must be changed accordingly. There is no calibration necessary, or possible, on the OEM-701 temperature circuits.

15.0 Suggested (Sample) Support Circuit for OEM-701