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# **Revision History**

REVISION	DATE	СОММЕНТ
Rev. 8	December, 2007	<ul> <li>Added design theme frame, BCI lozenge and Smiths Medical logo to front cover.</li> </ul>
		<ul> <li>Added Smiths design mark to trademark statement.</li> </ul>
		<ul> <li>Updated Warranty and Service Information section. Changed Warranty from one year to two years to match operation manual.</li> </ul>
		<ul> <li>Added Australian Representative to Warranty section and back cover.</li> </ul>
		Added About this Manual section to Chapter 1.
		Added WEEE Recycling instructions in symbol table in Chapter 1.
		Updated warnings, cautions and notes to match operation manual.
		<ul> <li>Updated Oximetry Theory of Operation and sensor chart in Chapter 3.</li> </ul>
		Updated email address.
		<ul> <li>Updated parts list in Chapter 9.</li> </ul>
		Moved Specifications section to its own chapter. (Chapter 10)
		Added desat study information to SpO2 Accuracy spec in chapter 10
		Added volume spec to Audible Alarm Indicators spec in Chapter 10.
		<ul> <li>Added Atmospheric Pressure spec to Environment Specs in Chapter 10.</li> </ul>
		<ul> <li>Updated format of Parts List, Assembly Drawings, and Schematics Appendix.</li> </ul>
		<ul> <li>Added company address and phone number to back cover.</li> </ul>

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# Warranty and Service Information

# **Proprietary Notice**

Information contained in this document is copyrighted by Smiths Medical PM, Inc. and may not be duplicated in full or part by any person without prior written approval of Smiths Medical PM, Inc. Its purpose is to provide the user with adequately detailed documentation to efficiently install, operate, maintain, and order spare parts for the device supplied. All information contained in this document is believed to be current and accurate as of the date of publication or revision, but does not constitute a warranty.

# Warranty

#### **Limited Warranty**

Smiths Medical PM, Inc. ("Seller") warrants to the original purchaser that the Product, not including accessories, shall be free from defects in material and workmanship under normal use, if used in accordance with its labeling, for two years from the date of shipment to the original purchaser.

Seller warrants to the original purchaser that the reusable oximeter sensors supplied as accessories, shall be free from defects in materials and workmanship under normal use, if used in accordance with its labeling, for one year from the date of shipment to the original purchaser (USA only).

#### **Disclaimer of Warranties**

#### THE FOREGOING EXPRESS WARRANTY, AS CONDITIONED AND LIMITED, IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES WHETHER EXPRESS OR IMPLIED, BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

Seller disclaims responsibility of the suitability of the Product for any particular medical treatment or for any medical complications resulting from the use of the Product. This disclaimer is dictated by the many elements which are beyond Seller's control, such as diagnosis of patient, conditions under which the Product may be used, handling of the Product after it leaves Seller's possession, execution of recommended instructions for use and others.

#### **Conditions of Warranty**

This warranty is void if the Product has been altered, misused, damaged by neglect or accident, not properly maintained or recharged, or repaired by persons not authorized by Seller. Misuse includes, but is not limited to, use not in compliance with the labeling or use with accessories not manufactured by Seller. This warranty does not cover normal wear and tear and maintenance items.

#### **Limitation of Remedies**

The original purchaser's exclusive remedy shall be, at Seller's sole option, the repair or replacement of the Product. THIS IS THE EXCLUSIVE REMEDY. In no event will Seller's liability arising out of any cause whatsoever (whether such cause is based on contract, negligence, strict liability, tort or otherwise) exceed the price of the Product and in no event shall Seller be responsible for consequential, incidental, or special damages of any kind or nature whatsoever, including but not limited to, lost business, revenues, and profits.

# Warranty Procedure

To obtain warranty service in the USA, you must request a Customer Service Report (CSR) number from Technical Service. Reference the CSR number when returning your Product, freight and insurance prepaid, to:

Smiths Medical PM, Inc.	Phone: (262) 542-3100
N7W22025 Johnson Drive	Fax: (262) 542-0718
Waukesha, WI 53186-1856	Toll Free: (800) 558-2345

Seller will not be responsible for unauthorized returns or for loss or damage to the Product during the return shipment. The repaired or replaced Product will be shipped, freight prepaid, to Purchaser.

To obtain warranty information outside of the USA, contact your local distributor.

Keep all original packing material, including foam inserts. If you need to ship the device, use only the original packaging material, including inserts. Box and inserts should be in original condition. If original shipping material in good condition is not available, it should be purchased from Smiths Medical PM, Inc.

Damages occurred in transit in other than original shipping containers are the responsibility of the shipper. All costs incurred returning devices for repair are the responsibility of the shipper.

# **CE Notice**

Marking by the symbol **0473** indicates compliance of this device to the Medical Device Directive 93/42/EEC.

Authorized Representative (as defined by the Medical Device Directive):

Smiths Medical International Ltd.Phone: (44) 1923 246434Colonial Way, Watford, Herts,Fax: (44) 1923 240273WD24 4LG, UKFax: (44) 1923 240273

Australian Representative:

Smiths Medical Australasia Pty. Ltd. Tel: +61 (0) 7 3340 1300 61 Brandl Street, Eight Mile Plains, QLD 4113, Australia

# Chapter 1: Introduction

# **About this Manual**

This manual contains circuit descriptions, voltage and waveform test points, detailed parts lists, and circuit diagrams for the monitor. It is intended for persons trained in service, maintenance, and repair of modern medical equipment. Thorough knowledge of this equipment's operation is required before attempting to repair this equipment.

# **Definition of Symbols**

SYMBOL	DEFINITION
	Type CF equipment
$\triangle$	Attention, see instructions for use.
Rx	Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
A	Refer servicing to qualified personnel.
%	On/Off
	Waveform/Trend or menu exit
Ø	Alarm Silence
%	Menu/Enter
~~	Up or Down arrows
۵	Alarm (LED)
-0:	External Power / Battery Eliminator LED
ETCO2	End Tidal Carbon Dioxide
八	RPM/Respiration Rate
♥bpm	Beats per minute (pulse rate)
%SPO2	Percent Oxygen Saturation
<b>A</b>	Breath indicator
Т	High Alarm Limit Indicator
	Low Alarm Limit Indicator
	Battery Gauge
$\rightarrow$	Input Voltage
<u> </u>	Printer Output
	Direct Current

SYMBOL	DEFINITION
	Non AP Device
	Date of Manufacture
IPX1	Drip Proof
SN	Serial Number
REF	Catalog Number
8	Do not reuse. One use on one patient.
Collect Separately	<b>Disposal (EU Countries)</b> Under the Waste Electrical and Electronic Equipment (WEEE) Directive 2006/96/EC and implementing regulations, all devices and service items within the scope of the Directive purchased new after August 13, 2005 must be sent for recycling when ultimately becoming waste. Devices and items must not be disposed of with general waste. If purchased before that date, they may also be sent for recycling if being replaced on a one-for-one, like-for- like basis (this varies depending on the country). Recycling instructions to customers using Smiths Medical products are published on the internet at: http://www.smiths-medical.com/recycle
	Disposal (other countries) When disposing of this device, its batteries or any of its accessories, ensure that any negative impact on the environment is minimized. Contact your local waste disposal service and use local recycling or disposal schemes. Separate any other parts of the equipment where arrangements can be made for their recovery, either by recycling or energy recovery. The main batteries are potentially harmful and will require separate disposal according to manufacturer's instructions or local regulations. Note: If applicable, EU, national or local regulations concerning waste disposal must take precedence over the above advice.

## Warnings, Cautions, and Notes

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

# **General Warnings**

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

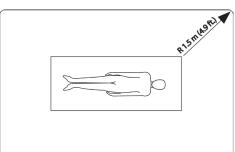
- WARNING! A Refer servicing to qualified personnel. ELECTRICAL SHOCK HAZARD when cover is removed. Unit not user serviceable.
- WARNING! Do not use this device in the presence of magnetic resonance imaging (MR or MRI) equipment.
- WARNING! Operation of this device may be adversely affected in the presence of computed tomograph (CT) equipment.

WARNING! Do not plug the monitor into an outlet controlled by a wall switch.

WARNING! This monitor is not for home use.

WARNING! This monitor is not intended for use in Sleep Study environments.

- WARNING! 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 monitor.
- 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! If the accuracy of any measurement is in question, verify the patient's vital sign(s) by an alternative method and then check the monitor for proper functioning.
- WARNING! Any monitor that has been dropped or damaged, should be inspected by qualified service personnel, prior to use, to insure proper operation.
- WARNING! Operation of this device may be adversely affected in the presence of conducted transients or strong EM or RF sources, such as electrosurgery and electrocautery equipment, x-rays, and high intensity infrared radiation.
- WARNING! When connecting to or communicating with this monitor, verify proper operation before clinical use. Refer to the instrument's user manual for full instructions. Accessory equipment connecting to or communicating 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 electro-medical equipment. All combinations of equipment must be in compliance with IEC 601-1-1 systems requirements.
- WARNING! IEC 950 approved equipment including the MCP8850B printer must be placed outside of the "patient environment". The patient environment is defined as an area 1.5m (4.92 feet) from the patient.



#### **Patient Environment**

- WARNING! In the event that earth ground integrity is lost, the performance of this device and/or other devices nearby may be affected due to excessive RF emissions.
- WARNING! Ensure the device's AC rating is correct for the AC voltage at your installation site before using the monitor. The monitor's AC rating is shown on the external power supply. If the rating is not correct, do not use the monitor; contact Smiths Medical PM, Inc. service department for help.
- WARNING! Disconnect the AC power supply from the outlet before disconnecting it from the monitor. Leaving the AC power supply connected to an AC power outlet without being connected to the monitor may result in a safety hazard.
- WARNING! Do not allow any moisture to touch the AC power supply connectors or a safety hazard may result. Ensure that hands are thoroughly dry before handling the AC power supply.

#### Chapter 1: Introduction

WARNING! Do not place the monitor in the patient's bed or crib. Do not place the monitor on the floor.

- WARNING! Failure to place the monitor away from the patient may allow the patient to turn off, reset, or damage the monitor, possibly resulting in the patient not being monitored. Make sure the patient cannot reach the monitor from their bed or crib.
- WARNING! If there is a risk of the AC power supply becoming disconnected from the monitor during use, secure the cord to the monitor several inches from the connection.
- WARNING! Patient safety can be compromised by the use of a power supply not be supplied by Smiths Medical PM, Inc. Use only the power supply included with your monitor, or approved by Smiths Medical PM, Inc.
- WARNING! The monitor should be operated from its internal power source if the integrity of the protective earth conductor is in doubt.
- WARNING! Remove device batteries prior to long term storage.
- WARNING! When using the AC battery eliminator, the Capnograph is a class II device with functional earth. This earth connection is for device electromagnetic compatibility and does not provide protection to the patient or user.
- WARNING! Do not autoclave, ethylene oxide sterilize, or immerse in liquid. Unplug the external power supply from the monitor before cleaning or disinfecting the monitor.
- WARNING! It is the operator's responsibility to set alarm limits appropriately for each individual patient.

#### **Capnograph Warnings**

- WARNING! Pump motors in the CO<sub>2</sub> monitor may adversely affect other medical equipment, e.g. ECG tracings.
- WARNING! The presence of anesthetic agents may cause CO<sub>2</sub> readings to deviate beyond specified tolerances.
- WARNING! This monitor is not for use as an apnea monitor.
- WARNING! The capnography parameter of this monitor is not for use on Neonates.

#### **Oximeter Warnings**

WARNING! Failure to carefully route the cable from the sensor to the monitor may allow the patient to become entangled in the cable, possibly resulting in patient strangulation. Route the cable in a way that will prevent the patient from becoming entangled in the cable. If necessary, use tape to secure the cable.

WARNING! Use only SpO<sub>2</sub> sensors supplied with, or specifically intended for use with, this device.

- WARNING! Incorrectly applied sensors may give inaccurate readings. Refer to the sensor insert for proper application instructions.
- WARNING! Prolonged use or the patient's condition may require changing the SpO<sub>2</sub> sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours.

- WARNING! When attaching SpO<sub>2</sub> sensors with Microfoam<sup>®</sup> 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! Dyes introduced into the bloodstream, such as methylene blue, indocyanine green, indigo carmine, patent blue V (PBV), and fluorescein, may adversely affect the accuracy of the SpO<sub>2</sub> reading.
- WARNING! 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 and SpO<sub>2</sub> readings.
- WARNING! Significant levels of dysfunctional hemoglobins, such as carboxyhemoglobin (with COpoisoning) or methemoglobin (with sulfonamide therapy), will adversely affect the accuracy of the SpO<sub>2</sub> measurement.
- WARNING! SpO<sub>2</sub> measurements may be adversely affected in the presence of high ambient light. If necessary, shield the sensor area (with a surgical towel, for example).
- WARNING! Optical cross-talk can occur when two or more sensors are placed in close proximity. It can be eliminated by covering each site with an opaque material.
- WARNING! Remove fingernail polish or false fingernails before applying SpO<sub>2</sub> sensors. Fingernail polish or false fingernails may cause inaccurate SpO<sub>2</sub> readings.
- WARNING! Tissue damage may result from overexposure to sensor light during photodynamic therapy with agents such as verteporphin, porfimer sodium and meta-tetrahydroxyphenylchlorin (mTHPC). Change the sensor site at least every hour and observe for signs of tissue damage. More frequent sensor site changes or inspections may be indicated depending upon the photodynamic agent used, agent dose, skin condition, total exposure time or other factors. Use multiple sensor sites.
- WARNING! Under certain clinical conditions, pulse oximeters may display dashes if unable to display SpO<sub>2</sub> and/or pulse rate values. Under these conditions, pulse oximeters may also display erroneous values. These conditions include, but are not limited to: patient motion, low perfusion, cardiac arrhythmias, high or low pulse rates, or a combination of the above conditions. Failure of the clinician to recognize the effects of these conditions on pulse oximeter readings may result in patient injury.

#### **General Cautions**

- CAUTION! Do not allow water or any other liquid to spill onto the monitor. Evidence that liquid has been allowed to enter the monitor voids the warranty.
- CAUTION! Should the device become wet, wipe off all moisture and allow sufficient time for drying before operating.
- CAUTION! Follow local governing ordinances and recycling instructions regarding disposal and recycling of device components.
- CAUTION! The monitor contains a 6-hour Lithium Ion (LI+) battery. If the battery fails to hold a charge or otherwise becomes inoperable, the battery should be replaced and the old battery should be disposed of properly. Consult local officials for information about the proper disposal of the Lithium Ion battery. Smiths Medical PM, Inc. cannot dispose of monitor batteries.

- CAUTION! Pressing front panel keys with sharp or pointed instruments may permanently damage the keypad. Press front panel keys only with your finger.
- CAUTION! Chemicals used in some cleaning agents may cause brittleness of plastic parts. Follow cleaning instructions in this manual.

# **Capnograph Cautions**

- CAUTION! Do not use the device without the appropriate filter attached. Use of any other filter will cause degradation in performance, and/or permanently damage the device.
- CAUTION! Use of monitor during continuous nebulized medication delivery will result in damage to the monitor (not covered by factory warranty). Disconnect the ETCO<sub>2</sub> sample line from the patient circuit or power monitor off during medication delivery.

#### Notes

- NOTE! All user and patient accessible materials are non-toxic.
- NOTE! Each input and output connection of the monitor is electrically isolated.
- NOTE! Performance and safety test data are available upon request.
- NOTE! To comply with government requirements for patient monitoring, the indefinite high priority alarm, medium priority alarm and low priority alarm tone silence feature may not be available in monitors shipped to your country.

# **Capnograph Notes**

- NOTE! InCO<sub>2</sub> is only displayed on the message line, and only if it has exceeded its alarm limit.
- NOTE! Capnograph patient attachments, sample lines, and filters are disposable, single-patient use items. Use a new patient attachment, filter and sample line for each new patient.
- NOTE! Discard and replace the patient attachment if it becomes occluded. If an air leak is noted, check all patient connections. If the air leak persists, discard and replace the patient attachment.

## **Oximeter Notes**

- NOTE! Alarm settings are maintained when power is turned off, except for the following.
- NOTE! The low SpO<sub>2</sub> alarm limit minimum test value is 80. If an operator changes the low SpO<sub>2</sub> alarm limit to a value less than 80, and a power down power up sequence takes place, a minimum value of 85 takes the place of the operator entered value.

# Chapter 2: Product Description

# **Intended use**

The Capnograph is a low-cost  $CO_2$  monitor with optional oximetry and optional external printer. It may be used in the hospital or clinical environment, and during emergency land transport. It is not intended for use in the home. It is intended to be used in all critical environments, including ventilatory applications, patient ground transport, EMS (Emergency Medical Services) and anesthesia. The capnography parameter provides end tidal  $CO_2$  (ET  $CO_2$ ) inspired  $CO_2$  (in  $CO_2$ ) and respiration rate measurements on all patients from pediatric to adult. The oximetry option works with all BCI<sup>®</sup> oximetry sensors, providing %SpO<sub>2</sub> and pulse rate on all patients from pediatric to adult. The Capnograph permits continuous patient monitoring with adjustable alarm limits as well as visual and auditory alarm signals. It is not intended nor designed to be used as an apnea monitor.

# **General Description**

The Capnograph is a portable handheld monitoring device. It provides side stream end tidal  $CO_2$  and  $SpO_2$  measurement capability.  $CO_2$  is measured with a self-contained low power  $CO_2$  sensor provided by CPT Inc.  $SpO_2$  measurements are made using the standard Smiths Medical PM, Inc. business card oximeter board. The parameters can be displayed in numerical and graphical format on a 160 x 160 pixel LCD display. Control of the unit is provided through a front panel keyboard. The unit is powered by a single 7.4V lithium-ion rechargeable battery.

The Capnograph circuitry is located on four assemblies: the main processor board (20652B1), the SpO<sub>2</sub> daughter board (71552B1), and the LCD display board (20653B1), and the front panel keyboard (20683B1). The main processor board operation is the subject of this document.

The main processor board is the most fundamental component in the system. All other circuit boards and components are considered peripherals to the main processor board. One of the design goals of the Capnograph was to incorporate as much on the main board as possible. The main board contains the CPU and memory for program execution, the drive circuitry for the display, pump, valve, and speaker, the interfaces for the SpO<sub>2</sub> daughter board, the CO<sub>2</sub> bench, ambient light detector, and external RS232 communications. The front panel interface circuitry is located on the main board. A series of power supply circuits to power all the above systems also reside on the board.

The 71552B1 oximetry board provides complete SpO<sub>2</sub> capability including the sensor interface, signal detection, SpO<sub>2</sub> and peripheral pulse rate calculation, waveform data and error and status codes. It is the same board that is used in the 9200 Advisor to provide SpO<sub>2</sub> functionality. The 71552B1 requires that the host system provide patient isolation. For a more detailed description of the operation of this assembly refer to the 71552B1 theory of operation.

The LCD display board (Smiths Medical PM, Inc. p/n 20653B1) provides the main display for the user interface. It is a 160x160 pixel LCD dot matrix display. Circuitry on the main processor board interface to the display board and control the display on a pixel by pixel basis. The 20651 provides an AC voltage signal for the EL backlight that is included in the PicView assembly. For more information refer to the 20653B1 PicView display documentation.

The front panel keypad provides pushbuttons used for user input and the front panel LED indicators. It is comprised of a combination of membrane switches and LED indicators fabricated on a flex circuit assembly. The membrane switches are a series of normally open, momentary switches. The main processor board responds to the closure of each switch. The LEDs located on the keypad assembly are driven by circuitry on the main processor board. For more information on the front panel keypad assembly, refer to the 20683B1 documentation.

# 20652B1 Main Processor Board

The main processor board is the main circuit board in the Capnograph system. It consists of the following sections:

#### **Power Supplies**

Battery voltage, +5V switching power supply, +5V bench linear supply, -V adjustable LCD bias voltage, -5VA.

#### **Microprocessor and Memory**

68HC812A4 μC, 128Kx16 Flash memory, 32Kx16 Static RAM.

#### **External Timer Circuitry**

 $\mu$ PD71054L three channel timer chip.

**Printer Interface** PIC12C508 μC, IR LED drive.

#### Front Panel Interface

Switch input, LED drive, protection circuitry.

#### **Ambient Light Interface** OPT101 light to voltage converter.

**Bench** CPT COMET bench.

#### **Analog Acquisition Circuitry** CO2 signal amplifier, voltage reference, 4 channel A/D converter.

**Display Interface** SED1335 display controller, 8Kx8 SRAM, high voltage EL drive.

#### Speaker drive circuitry

Tone, volume, slew rate control.

**Pump Control** High current drive.

Valve Control High, low current drive.

#### **Serial Interface** Printer channel, SpO<sub>2</sub> interface, data logging.

# **Power Supplies**

The Capnograph is powered by a single 7.4V Lithium Ion battery. A high efficiency step down DC-DC converter is used to generate +5V from the battery voltage. The +5V powers all of the digital circuitry, the display, the pump, valve and speaker drive circuitry, and the SpO<sub>2</sub> daughter board.

The +5V provides the input for an adjustable negative power supply. The range of the negative supply is -5V to -15V. This voltage is required for the LCD display and the voltage controls the contrast of the LCD display. The output voltage of this switching regulator is controlled by the LCDCK and LDIR signals.

This negative voltage is linearly regulated to -5V with a linear voltage regulator. This voltage is required by the SpO<sub>2</sub> board.

#### **Microprocessor and Memory**

The Motorola 68HC812A4 processor provides a low power, fully integrated solution to the overall design of the Capnograph. The 68HC812A4 is run in 16 bit wide mode which means that instructions are fetched 16 bits at a time. A single 16 bit wide Flash memory device is used to store program code, trend data, and non-volatile setup information. A single 16 bit wide static RAM (KM164000B) is used for program data space. The 68HC812A4 generates its own chip selects and bus timing signals.

An on board 8 bit A/D converter is used to convert ambient light and battery voltages.

The 68HC812A4 has an on chip background debugger capability that is used for code development and test. The background debug pins are located on connector J7.

#### **External Timer Circuitry**

Three channels of digital timer functionality are provided with the  $\mu$ PD71054L timer chip. The timer chip clock input is driven by the 68HC812A4 E clock.

One timer channel is used to generate the Microchip PIC clock. The second channel is used to generate the speaker tone. The third channel is used to generate the display synchronization signal to the processor.

#### **Printer Interface**

The interface to the Martel MCP8850B thermal printer is provided by the PIC12C508 microcontroller. The PIC receives serial characters from the 68HC812A4 and converts them into the communications format that the Martel printer requires. The output of the PIC drives a transistor that boosts the current drive for the IR LED.

#### **Front Panel Interface**

The front panel keyboard assembly connects to the main circuit board via J4 and J14. The keyboard includes switches for ON/OFF, Waveform Select, Alarm Silence, Menu/Enter, Up and Down keys. Each of the keys on the keypad are normally open momentary single pole switches.

The assembly also contains 3 LEDs for displaying ETCO<sub>2</sub> alarm, SpO<sub>2</sub> alarm, and external power connection. The circuitry on the main circuit board drives the LEDs at the proper current levels. P-channel FETs are used to drive the LEDs. The control signals that drive the FET gates are active low signals.

The circuitry surrounding the switch and LED drive connections protect the main board from potential static discharge that is possible through the keyboard.

#### **COMET CO<sub>2</sub> Sensor (Bench)**

The main  $CO_2$  sensor for the Capnograph is the COMET  $CO_2$  bench manufactured by Treymed (formerly CPT, Inc.). The bench produces an output voltage that is proportional to the concentration of  $CO_2$  in the sample cell. Sample cell barometric pressure is provided with an on bench pressure sensor. Sample cell temperature is provided with an on bench temperature sensor.

The CO<sub>2</sub> bench also includes an on bench EEPROM that contains factory calibration values. These values are read by the Capnograph at power up. The EECS, EECLK, EEDAT signals are used to communicate with the bench EEPROM. Raw CO<sub>2</sub>, pressure and temperature values are manipulated with the EEPROM constants to provide calibrated CO<sub>2</sub> Pressure and temperature values.

## **Analog Acquisition Circuitry**

The raw CO<sub>2</sub> signal that is provided by the COMET bench is amplified with a non-inverting amplifier stage with a gain of 6.2. The temperature and pressure signals do not have any gain circuitry in the signal path.

The analog signals produced by the bench and amplifier circuitry are converted to digital codes with a 12 bit 4 channel A/D converter. The converter is also driven with a 4.096V voltage reference. This combination provides a conversion factor of 1 bit/mV of input signal for each channel.

#### **Display Interface**

The display controller circuitry utilizes the S-MOS SED1335 Display controller. This controller uses an 8- bit data bus along with several control signals and an address line from the processor. The controller uses a 10 MHz crystal to generate its system clock. This provides the maximum throughput to the display.

The graphics controller uses a 32Kx8 SRAM chip for its display memory. This memory is separate from the RAM used by the 68HC812A4. This configuration allows refresh of the display without affecting main processor bandwidth.

The host interface to the graphics RAM is through the display controller. The host sends a command to the controller for accessing the display RAM. The controller then writes/reads the data to/from the host processor. This graphics access reading/writing process is tightly controlled in software to avoid pixel flicker on the display.

The following signals make up the display controller interface to the LCD panel connections:

- XD0 to XD3 are the 4-bit X-driver (column drive) data outputs. These outputs are connected to the inputs of the X-driver chips.
- XSCL latches the data on XD0 to XD3 into the input shift registers of the X-drivers on its falling edge. To conserve power, this clock halts between LP and the start of the following display line.
- LP latches the signal in the X-driver shift registers into the output data latches. LP is a falling-edge triggered signal and it pulses once every display line. The LP is connected to the external interrupts through a logical NAND gate. The NAND gate's other input is used to mask off/on the interrupt when used in conjunction with the processors /NMI input.
- WF is the LCD panel AC drive output. The WF period is selected to be one of two values with SYSTEM SET command.
- YD is the data pulse output for the Y drivers. It is active during the last line of each frame. Data is shifted through the Y drivers be YSCL one by one to scan the display's common connections.
- YDIS is the display power-down output signal. YDIS is HIGH while the display drive outputs are active.

#### **Speaker Drive Circuitry**

The speaker drive circuitry drives the speaker with a fundamental tone and harmonics. The circuitry has the capability of controlling the on/off slew rate of the tone as well as the volume.

The fundamental frequency is determined by the frequency of the TONE signal generated by the timer chip. SPKRON controls the on/off action of the speaker. /FSLEW controls the slew rate of the on/off ramp. CLICK is used to provide a key click sound when a key is pressed. The signal VOL\_PWM is ended with the TONE signal to provide a PWM style volume control.

#### **Pump Control**

The pneumatic pump used to pull gas through the  $CO_2$  bench is a +5VDC pump. It is turned on and off with a P channel MOSFET. When the PUMPON signal generated by the 68HC812A4 goes to its active state, the MOSFET is turned on and 5V is applied across the pump terminals and the pump runs.

#### **Valve Control**

The pneumatic valve used to switch the flow of  $CO_2$  scrubbed ambient gas or sample line gas to the  $CO_2$  bench. The valve is normally in the sample position. Energizing the valve selects the  $CO_2$  scrubbed ambient gas to pass to the sample chamber in the  $CO_2$  bench.

The control circuitry is similar to the pump drive circuitry. However the valve drive circuitry has a two stage drive circuit configuration. The first stage is made up of a high current P channel MOSFET. When the VALVON signal is sent active low, the high current drive MOSFET is turned on and the valve is connected directly to the 5V supply. This gets the valve to the energized state quickly. At the same time that the high current MOSFET is turned on, the lower current P channel MOSFET is turned on. This circuit also connects the valve to the +5V supply. In this circuit path there is a 50 ohm resistance. This resistance limits the current through the valve and therefore the power dissipated by the valve. The valve need less current to keep it in the on state and the lower current MOSFET channel is all that is needed.

#### **Serial interface**

The main processor board provides two channels of asynchronous serial communications capability. One channel is used for bi-directional communication between the 68HC812A4 and the SpO<sub>2</sub> daughter board. The second serial channel is used for unidirectional communication to the PIC12C508. Data is transferred from the 68HC812A4 to the PIC. The PIC converts the serial data into the HP-compatible printer format for the Martel printer.

An additional feature of the serial communication circuitry is that through the selection of the DIP switches, the second serial channel can be routed to provide data logging through the serial channel.

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# **Chapter 3: Pulse Oximetry**

# **Product Description**

The BCI<sup>®</sup> 71552B1 Pulse Oximeter Board from Smiths Medical PM, Inc. enables easy OEM integration for fast, reliable SpO<sub>2</sub> and Pulse Rate measurements on any patient, from neonates to adults. Serial communication at 4800, 9600 or 19,200 Baud provides the host system with %SpO<sub>2</sub>, 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 71552B1 Pulse Oximeter has a compact size of 8.9 cm (3.5 inches) wide by 5.1 cm (2.0 inches) deep by 1.3 cm (0.5 inch) high. An assortment of compatible Oximeter probes and patient attachments are available through Smiths Medical PM, Inc.

Inspect all patient cables, leads, and sensors, for general condition. Should they exhibit signs of excessive wear or damage, please replace.

# **Pulse Oximetry Theory of Operation**

The pulse oximeter determines %SpO<sub>2</sub> and pulse rate by passing two wavelengths of low intensity light, one red and one infrared, through body tissue to a photodetector. Information about wavelength range can be especially useful to clinicians. Wavelength information for this device can be found in the SpO<sub>2</sub> Specifications section of this manual.

Pulse identification is accomplished by using plethysmographic techniques, and oxygen saturation measurements are determined using spectrophotometric oximetry principles. 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.

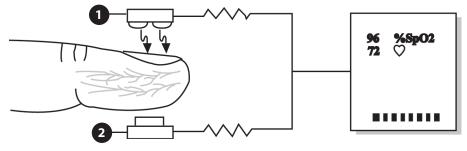


Figure 3.1: Pulse Oximetry Theory of Operation

#### Low intensity Red and Infrared LED light sources

# 2 Detector

Oximetry 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<sub>2</sub>) to identify the pulses and calculate functional oxygen saturation. Oxygen saturation calculations can be performed because blood saturated with oxygen predictably absorbs less red light than oxygen-depleted blood.

# WARNING! Since measurement of SpO<sub>2</sub> depends on a pulsating vascular bed, any condition that restricts blood flow, such as the use of a blood pressure cuff or extremes in systemic vascular resistance, may cause an inability to determine accurate SpO<sub>2</sub> and pulse rate readings.

WARNING! Under certain clinical conditions, pulse oximeters may display dashes if unable to display SpO<sub>2</sub> and/or pulse rate values. Under these conditions, pulse oximeters may also display erroneous values. These conditions include, but are not limited to: patient motion, low perfusion, cardiac arrhythmias, high or low pulse rates or a combination of the above conditions. Failure of the clinician to recognize the effects of these conditions on pulse oximeter readings may result in patient injury.

# **Product Specifications**

#### Data Provided to the Host System

SpO <sub>2</sub>	
------------------	--

A	0	0-100% ± 2 % at 70 - 100% SpO <sub>2</sub> ± 3 % at 50 - 69% SpO <sub>2</sub>
Pulse Rate		
	Range:	30 - 250 BPM
A	ccuracy:	± 2BPM at 30 - 250 BPM
Signal Strength:		0 - 8 (Protocol #1 and Protocol #2)
Bargraph:		0 - 15 (0 - 16 for Protocol #3)
Plethysmogram:		0 - 100, auto-gained for highest resolution. 8-bit and 16-bit waveforms available.
Flags:		Pulse Beep No Finger in Probe Probe Unplugged Searching for Pulse Searching Too Long
Software Revision:		transmitted upon request
Serial Communication Logic	: Levels:	TTL voltage levels

# Data Provided From the Host System (Protocol #1 and Protocol #2)

SpO <sub>2</sub> 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 or Performed Automatically

# Data Provided From the Host System (Protocol #3)

Set Waveform Rate:	Can be set from 10 msec to 247.5 msec in 2.5 msec increments.
Waveform Rate Request:	Ranges from 10 msec to 247.5 msec in 2.5 msec increments.
Set Response Mode:	Normal (default), fast, or slow mode.
Response Mode Request:	Normal, fast, or slow mode.
Restart Oximeter:	Restores all default values (same as power on reset)
Version Request:	Responds with version string.
Primary Status Request:	Probe/No Probe attached, pulse search
Secondary Status Request:	Waveform On/Off, 8-bit/16-bit waveform
Enable 16 bit Waveform:	Must restart Oximeter to disable

## **Power Requirements**

Power Supply Input Voltage (typical):	+5 VDC Digital @ 35mA electrically isolated
	+5 VDC Analog @ 16mA electrically isolated
	-5 VDC Analog @ 5mA electrically isolated

## Dimensions

Width:	8.9 cm (3.5 inches)
Depth:	5.1 cm (2.0 inches)
Height:	1.3 cm (0.5 inches)

# **Serial Communications Specifications**

The 71552B1 Pulse Oximeter board communicates with the host computer through a single, high-speed asynchronous serial channel at TTL voltage levels. Data provided to the host includes %SpO<sub>2</sub>, Pulse Rate, Signal Strength, Bargraph, Plethysmogram, and Status Bits data. The host can send commands to control the averaging rates, synchronize the Plethysmogram Waveform, and request the Oximeter software revision level. Three protocol options are provided for system flexibility. These protocols are hardware jumper selected.

#### **Communication Protocols**

There are 3 protocols available on the 71552B1 Pulse Oximeter Board which support the BCI<sup>®</sup> Oximetry Communications Protocol. Jumper settings for each protocol and available baud rates are shown in the table below.

	BAUD	SERIAL PORT SETTINGS PARITY-DATA-STOP	BYTES PER PACKET	PACKETS PER SEC	JUMPER J3 - 1	JUMPER J3 - 2	JUMPER J3 - 3
Protocol #1	4800	O-8-1	5	60	OFF	OFF	OFF
Protocol #1	9600	O-8-1	5	60	ON	OFF	OFF
Protocol #2	19200	E-8-1	8	120	OFF	ON	OFF
Protocol #3	9600	E-8-1	Variable	Variable	OFF	OFF	ON
Protocol #3	19200	E-8-1	Variable	Variable	ON	OFF	ON

#### **Communication Protocol #1**

Data is transmitted from the Oximeter board to the host at a rate of 60 packets per second. Data is formatted in 5-byte packets. Data packets transmitted from the Oximeter to the host can be synchronized by using bit 7. The communication settings are 4800 or 9600 Baud, One Start Bit, Eight Data Bits, Odd Parity, One Stop Bit.

#### **Communication Protocol #2**

Data is transmitted from the Oximeter board to the host at a rate of 120 packets per second. Data is formatted in 8-byte packets. Data packets transmitted from the Oximeter to the host can be synchronized by using bit 7. The communication settings are 19200 Baud, One Start Bit, Eight Data Bits, Even Parity, One Stop Bit.

#### **Communication Protocol #3**

Data is transmitted from the Oximeter board to the host at a rate defined by the host system. Fast data is formatted in 4-byte packets. Slow data packets will vary in length. The communication settings are 9600 or 19200 Baud, One Start Bit, Eight Data Bits, Even Parity, One Stop Bit. This communication protocol is available upon request.

#### Serial Communication Notes - Protocol #1 and Protocol #2

• Start up averaging is:

SpO<sub>2</sub>: 8 pulses

HR: 8 seconds

- To synchronize Plethysmogram level and offset algorithm, the 'A' command is used. After start up, auto pleth size/offset is enabled, and the board periodically adjusts the Plethysmogram level to keep the waveform in range using the processor's internal timer. If command 'G' is sent, the internal timer is disabled, and the Master can adjust the Plethysmogram by sending the 'A' command. This command makes the board run an adjustment algorithm once, to make sure that during the next time interval the Plethysmogram will stay in range. For example, one could send this command between the Master's screen "frames" to make sure that during the display of any given frame there will not appear to be any "jumps" on the waveform.
- 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 Master has not received revision information yet from previous 'E' command, the next 'E' command will be lost. "Revision level" response interrupts the normal data stream at any place. It is assumed that the '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 probe). Invalid data can be interpreted as:

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

# **Oximeter Transmitted Data – Protocol #1**

Data is transmitted from the Oximeter board to the Host in 5-byte packets. Baud rate is jumper selectable for 4800 or 9600 baud.

BYTE	BIT	DESCRIPTION
1	0	Signal Strength 0
	1	Signal Strength 1
	2	Signal Strength 2
	3	Signal Strength 3
	4	1 = searching too long
	5	1 = probe unplugged
	6	1 = pulse beep
	7	1 (sync. bit)
2	0	Plethysmogram 0
	1	Plethysmogram 1
	2	Plethysmogram 2
	3	Plethysmogram 3
	4	Plethysmogram 4
	5	Plethysmogram 5
	6	Plethysmogram6
	7	0 (sync. bit)
3	0	Bargraph 0
	1	Bargraph 1
	2	Bargraph 2
	3	Bargraph 3
	4	1 = no finger in probe or probe unplugged
	5	1 = searching for pulse
	6	Rate 7 (see byte 4)
	7	0 (sync. bit)

BYTE	BIT	DESCRIPTION
4	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)
5	0	SpO <sub>2</sub> 0
	1	SpO <sub>2</sub> 1
	2	SpO <sub>2</sub> 2
	3	SpO <sub>2</sub> 3
	4	SpO <sub>2</sub> 4
	5	SpO <sub>2</sub> 5
	6	SpO <sub>2</sub> 6
	7	0 (sync. bit)

NOTE: When a lost pulse condition is detected by the board, it will send the Lost Pulse Alarm Flag by setting both bit 4 (Searching Too Long) of byte 1 and bit 4 of byte 3 (No Finger in Probe).

# Oximeter Transmitted Data – Protocol #2

Data is transmitted from the Oximeter board to the Host in 8-byte packets. The baud rate is 19,200 baud. The checksum is a 14-bit number specified as a 2's complement of the sum of the first 6 bytes of the data packet.

BYTE	BIT	DESCRIPTION		BYTE	BIT	DESCRIPTION
1	0	Signal Strength 0		5	0	SpO <sub>2</sub> 0
	1	Signal Strength 1	]		1	SpO <sub>2</sub> 1
	2	Signal Strength 2			2	
	3	Signal Strength 3				SpO <sub>2</sub> 2
	4	1 = searching too long			3	SpO <sub>2</sub> 3
	5	1 = probe unplugged			4	SpO <sub>2</sub> 4
	6	1 = pulse beep			5	SpO <sub>2</sub> 5
	7	1 (sync. bit)			6	SpO <sub>2</sub> 6
2	0	Plethysmogram 0			7	0 (sync. bit)
	1	Plethysmogram 1		6	0-1	1
	2	Plethysmogram 2			01	00 = 4 beat average SpO <sub>2</sub> 8 beat average Pulse Rate
	3	Plethysmogram 3				01 = 8 beat average SpO <sub>2</sub>
	4	Plethysmogram 4				8 beat average Pulse Rate
	5	Plethysmogram 5				10 = 16 beat average SpO <sub>2</sub> 16 beat average Pulse Rate
	6	Plethysmogram 6				11 = 16 beat average SpO <sub>2</sub>
	7	0 (sync. bit)				8 beat average Pulse Rate
3	0	Bargraph 0			2	Unused
	1	Bargraph 1			3	Unused
	2	Bargraph 2			4	1 = Revision Level Reply
	3	Bargraph 3			5	Unused
	4	1 = no finger in probe or probe			6	1 - Disable Auto Pleth Scaling
		unplugged			7	0 (sync. bit)
	5	1 = searching for pulse		7	0 - 6	Checksum Bits 0 - 6
	6	Rate 7 (see byte 4)			7	0 (sync. bit)
	7	0 (sync. bit)	4	8	0 - 6	Checksum Bits 7 - 13
4	0	Rate 0			7	0 (sync. bit)
	1	Rate 1				
	2	Rate 2				
	3	Rate 3				
	4	Rate 4				
	5	Rate 5				
	6	Rate 6				
	7	0 (sync. bit)				

# **Oximeter Received Data – Protocol #1 and Protocol #2**

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 is automatically adjusted every 256 samples.	
В	Sets SpO <sub>2</sub> to 4-beat average and pulse rate to an 8-second average.	
С	Sets SpO <sub>2</sub> to 8-beat average and pulse rate to an 8-second average (default).	
D	Sets SpO <sub>2</sub> to 16-beat average and pulse rate to a 16-second average.	
E	<ul> <li>Forces Oximeter to send software revision level (x.xx) in a 5-byte format:</li> <li>Byte 1: 80H</li> <li>Byte 2: (00H for protocol #2) (FFH for protocol #1)</li> <li>Byte 3: Ones digit (ASCII)</li> <li>Byte 4: Tenths digit (ASCII)</li> <li>Byte 5: Hundredths digit (ASCII)</li> </ul>	
F	Sets SpO <sub>2</sub> to 16-beat average and pulse rate to an 8-second average.	
G	Disable automatic Plethysmogram scale and offset	
н	Enable automatic Plethysmogram scale and offset	

# Serial Communication Notes – Protocol #3

Protocol #3 communicates using a method that combines two message types: slow and fast. Slow data packets are used to communicate commands and status messages in a bi-directional manner between the module and the host system. Fast data packets are used to send pulse and waveform data in a timely manner from the module to the host. Slow data packets can contain more than one message. Fast data packets always contain only one message.

# **Slow Data Packet Format**

Every slow data packet is transmitted with the following format:

DATA DESCRIPTION	FORMAT
{STX}	(0x02)
Message Length	(2 ASCII characters)
Reserved Byte	(0x20)
Slow Data Messages Checksum	(2 ASCII characters)

The message length is in hex notation and has a max value of FF (255). The length is just the length of the data messages. It does not include the reserved byte or the checksum. The checksum is determined from the message length bytes, reserved byte and data message bytes. It is the 2's complement of the modulo-256 sum of the bytes expressed in hex form.

# **Slow Data Message Format**

The contents of the slow data packet is made up of multiple slow messages. The slow message format is:

Message Identifier	(1 byte)	
Data Length	(2 ASCII characters)	
Message Data	(variable length)	

The following messages are supported in the BCI<sup>®</sup> 71552B1 Oximeter:

From the Oximeter:

P00	Pulse S	earching, transmitted every ¼ second when active.				
T00	Pulse Searching Too Long, transmitted every 10 seconds when active					
X00	Probe Off, transmitted every ¼ second when active					
W02xx	Wavefo 99.	Waveform Rate, W00 command response. xx is the current waveform rate and ranges from 0 to 99.				
M01x		Response Mode, M00 command response. $X = 1$ , 2 or 3 for Normal, Fast and Slow mode, respectively.				
VLLxxx		n, V00 command response. LL = message length, xxx version string; <i>XX_mm/dd/yy</i> where ersion number x.x				
S02xx	Primary where:	y Status, S00 command response. xx is decimal ASCII representation of a bitmapped value				
	bit 0	0=no probe, 1=probe attached				
	bit 1	0				
	bit 2	0=no pulse search, 1=pulse search				
	bit 3	1				
	bit 4	0				
	bit 5	0				
	bit 6	0				
	bit 7	0				
s02xx	Secondary Status, s00 command response. xx is decimal ASCII representation of a bitmapped value where:					
	bit 0 0=waveform on (default), 1=waveform off					
	bit 1 0=8-bit waveform (default), 1=16 bit waveform					
	bit 2	0				
	bit 3	0				
	bit 4	0				
	bit 5	0				
	bit 6	0				
	bit 7	0				
E01x	Error, s	ent in response to various messages. x is defined as follows:				
	1 = RAI	M error (Oximeter stops)				
	2 = RO	M Checksum Error (Oximeter stops)				
	3 = Last Message had Checksum Error (message ignored)					
	5 = Command value out of range (command ignored)					
	9 = Command syntax error (command ignored)					

To the Oximeter:

W02xx	Set Waveform Rate. xx is the current waveform rate and ranges from 4 to 99. Rate is 2.5ms per sample times xx. 4=10ms, 99=247.5ms. The default rate is 4 (10ms). A W010 command causes waveform output to stop.	
W00	Waveform Rate Request.	
M01x	Set Response Mode. $x = 1$ , 2 or 3 for Normal, Fast and Slow mode, respectively. The default mode is Normal.	
M00	Response Mode Request.	
A00	Restart Oximeter.	
V00	Version Request.	
S00	Primary Status Request.	
s00	Secondary Status Request.	
w00	Enable 16 bit waveform output (there is no disable command other than a restart)	

# Fast Data Message Format

Fast data messages are always four bytes in length. Every fast data message is transmitted with the following format:

DATA DESCRIPTION	FORMAT
{DLE}	(0x10)
Message Identifier	(1 ASCII character)
Message Data	(2 bytes)

Fast messages can occur at any time including during the transmission of slow data packets. When sent during a slow packet transmission they do not affect the length of checksum of the slow packet.

There are three valid fast data messages:

!	SpO <sub>2</sub> and Pulse Rate Values are sent once per pulse. 1st data byte is SpO <sub>2</sub> value, 2nd data byte is pulse rate value.
~	Pulse waveform and pulse bargraph values are sent at the programmed waveform rate. 1st data byte is pulse waveform from 0 to 255. 2nd data byte is pulse bargraph from 0 to 16.
+	Full scale (16 bit) pulse waveform values are sent at the programmed waveform rate. 1st byte is the LSB, 2nd byte is the MSB. Data values range from 0 to 65535.

# Pin Description for 71552B1

# J1 - Power and Communication Connector

PIN	DESCRIPTION
1	No Connect
2	GND
3	GND
4	/RESET Input
5	GND
6	No Connect
7	-5VDC Analog Input
8	TX Output
9	RX Input
10	+5VDC Analog Input
11	/CTS Input
12	GND
13	+5VDC Digital Input
14	GND

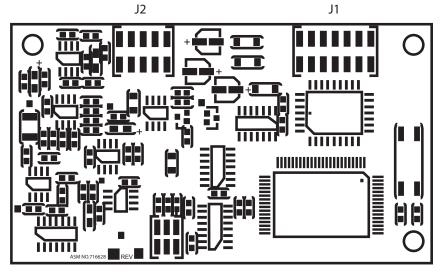
## J2 - Oximeter Probe Connector

J2 PIN	SMITHS MEDICAL PM, INC. CABLE COLOR CODE	DB9 PIN
1	White	5
2	No Connect	
3	No Connect	
4	Black	9
5	Yellow	6
6	Green	1
7	Orange	3
8	No Connect	
9	Red	2
10	Shield	7

# Jumper Settings for 71552B1 Board

Jumper Settings are used to select communication modes.

	BAUD	JUMPER J3-1	JUMPER J3-2	JUMPER J3-3
Protocol #1	4800	OFF	OFF	OFF
Protocol #1	9600	ON	OFF	OFF
Protocol #2	19200	OFF	ON	OFF
Protocol #3	9600	OFF	OFF	ON
Protocol #3	19200	ON	OFF	ON
Factory Test	19200	ON	ON	ON



3 2 1 JUMPER 3

# Sensors

Choose the appropriate sensor from the following chart.

PATIENT	SITE	CAT. NO. & DESCRIPTION
Adult	Finger	3044: Sensor, Adult (reusable)
>45 kg		3444: Sensor, Comfort Clip <sup>®</sup> (reusable)
	Finger or Toe	3043: Sensor, Universal 'Y' (reusable)
		1300: Sensor, Adult (disposable) 🕥
	Ear	3078: Sensor, Ear (reusable)
Pediatric	Finger	3044: Sensor, Adult (reusable) (>20 kg)
15-45 kg		3444: Sensor, Comfort Clip® (reusable)
		3178: Sensor, Pediatric (reusable) (5-45 kg)
	Finger or Toe	3043: Sensor, Universal 'Y' (reusable)
		1301: Sensor, Pediatric (disposable) 🕥
	Ear	3078: Sensor, Ear (reusable)
Infant	Hand or Foot	3043: Sensor, Universal 'Y' (reusable)
3-15 kg	Toe	3025: Sensor, Wrap, Infant (reusable)
	Finger or Toe	1303: Sensor, Infant (disposable) 🛞
Small Infant < 3 kg	Hand or Foot	1302: Sensor, Neonate (disposable) 🛞
< 3 kg	Foot	3026: Sensor, Wrap, Neonate (reusable)

\* The BCI<sup>®</sup> 1302 and 3026 oximetry sensors should not be used on neonatal patients with the Capnograph monitor. Testing has not been conducted for the Capnograph for patients less than 30 days old. These sensors may, however, be used on older patients.

# **Checking the Oximeter's Performance**

Pulse oximeters do not require user calibration. If checking the function of the device is desired, an optional Oximetry/ECG Patient Simulator (SMPM catalog number 1606) is available as an accessory. The simulator attaches to the oximeter in place of the sensor or oximetry cable. It provides a known SpO<sub>2</sub> and pulse rate signal to the oximeter. This allows the oximeter's performance to be checked.

- NOTE! The 1606 Oximetry/ECG Patient Simulator does not calibrate the monitor; the monitor does not require calibration. The 1606 provides a known SpO<sub>2</sub> and pulse rate to the monitor that allows you to check the monitor's performance.
- NOTE! The 1606 Oximetry/ECG Patient Simulator cannot be used to assess the accuracy of a pulse oximeter and/or sensor.

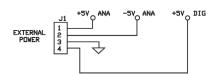
NOTE: A Follow the instructions included with the 1606 Oximetry/ECG Patient Simulator.

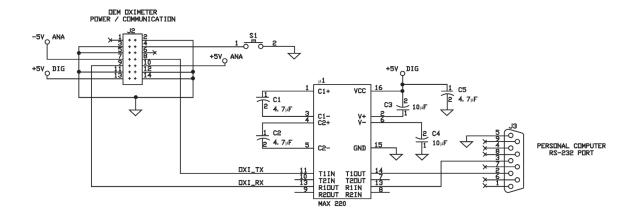
# **Demonstration Software**

**Smiths Medical PM, Inc. provides PC software for demonstration purposes only.** The intent is to allow the OEM customer to quickly become familiar with the operation of the Oximeter board. **This software is NOT 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 an SpO<sub>2</sub> simulator. Do not connect directly to a patient without proper patient isolation.** Command line help is given if no command line options are used for OEM.EXE or ADV.EXE. PROT3.EXE is a "Windows" based program with a menu driven user interface.

	DEMONSTRATION SOFTWARE
Protocol #1	OEM.EXE
Protocol #2	ADV.EXE
Protocol #3	PROT3.EXE

The 71552 Oximeter board 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.





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### Chapter 4: CO<sub>2</sub> Theory of Operation

### Theory of Operation

#### **Measuring CO<sub>2</sub>**

The device draws a sample of gas through the sample chamber. A light source shines infrared (IR) light through an optical bandpass filter and then through the sample chamber. An IR detector responds to the amount of IR light that passes through the sample chamber.

Because  $CO_2$  absorbs IR light at a specific wavelength, the amount of light passing through the sample chamber varies according to the concentration of  $CO_2$  in the sample chamber. When there is a high concentration of  $CO_2$  in the sample chamber, the detector senses a smaller amount of light than when there is a low concentration of  $CO_2$ .

The device computes the partial pressure of CO<sub>2</sub> STPD (standard temperature, pressure, dry) based on measured levels of IR light intensity. The ETCO<sub>2</sub> measurement is shown as an average of 4 breaths.

# CAUTION! Pump motors in the CO<sub>2</sub> monitor may adversely affect other medical equipment, e.g. ECG tracings.

#### **Measuring Respiration Rate**

The device uses the continuous  $CO_2$  waveform to detect each breath cycle. It uses an adaptive algorithm to recognize each breath in the waveform, even in the presence of an elevated baseline (rebreathing) and higher frequencies in the  $CO_2$  waveform (cardiogenic oscillations).

The device computes respiration rate (RPM) from the total number of seconds for the last four breaths according to this formula:

$$RPM = \frac{60 \text{ seconds x breaths}}{\text{Number of seconds for 4 breaths}}$$

#### N<sub>2</sub>O Compensation

The interfering effect of  $N_2O$  results in inaccurate  $CO_2$  readings, however the device has the ability to compensate for this.

With the N<sub>2</sub>O compensation ENABLED, the device adjusts the CO<sub>2</sub> reading by an algorithm that assumes the concentration of N<sub>2</sub>O is 40% and compensates accordingly. If N<sub>2</sub>O compensation is enabled and the concentration of N<sub>2</sub>O is not 40%, the displayed value must be adjusted by the following equation to get the actual CO<sub>2</sub> concentration:

Actual CO2 = 
$$\frac{\text{CO2 Reading x 1.0625}}{1 + \left(\frac{0.0625 \times \text{N2O\%}}{40\%}\right)}$$

With the N<sub>2</sub>O compensation DISABLED, the device adjusts the CO<sub>2</sub> reading by an algorithm that assumes the concentration of N<sub>2</sub>O is 0%. If N<sub>2</sub>O compensation is disabled and the concentration of N<sub>2</sub>O is not 0%, the displayed value must be adjusted by the following equation to get the actual CO<sub>2</sub> concentration:

Actual CO2 = 
$$\frac{\text{CO2 Reading}}{1 + \left(\frac{0.0625 \times \text{N2O\%}}{40\%}\right)}$$

NOTE! The presence of other anesthetic agents may cause CO<sub>2</sub> readings to deviate beyond specified tolerances.

### **Chapter 5: Pneumatics and CO<sub>2</sub> Calibration**

#### **Connecting a Non-Recirculating Scavenging System**

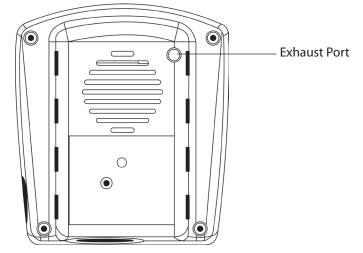


Figure 5-1: Connecting a Non-recirculating Scavenging System

#### **Exhaust Port**

Connect tubing to exhaust port.

If desired, connect a non-recirculating scavenging system to the exhaust port on the monitor's rear panel as shown.

#### CAUTION! When connecting a non-recirculating scavenging system, only use an exhaust line approved by Smiths Medical PM, Inc. Failure to comply may result in damage to the monitor.

### **Checking for Leaks**

- 1. Pinch the sample line near the moisture filter connection.
- 2. Make sure the "**OCCLUSION**" message appears in the lower left of the display. If no message appears, go to *Chapter 8: Troubleshooting* in this manual.

### **Calibrating the Capnograph**

Calibration ensures that the ETCO<sub>2</sub> and Inspired CO<sub>2</sub> measurements are accurate. Calibrate the device every 30 days.

NOTE! Use only the calibration gas canister and flow regulator supplied with or specifically intended for use with this device. See *Chapter 9: Supplies and Accessories* in this manual for information on ordering calibration gas.

The device has two calibration modes: Low Calibration (LO CAL) and Low/High Calibration (LO/HI CAL). The LO CAL process is required if a significant change in altitude occurs. It is not necessary to remove the device from the patient while performing a LO CAL procedure because a three-way valve closes the patient inlet and opens to room air. The LO/HI CAL procedure requires the delivery of a gas mixture from a canister.

#### WARNING! Remove the device from the patient before performing a Calibration procedure.

#### **Low Calibration**

To perform a LO CAL, do the following:

- 1. Turn on the device.
- 2. Depress the **MENU/ENTER** (%) key. Select **Capnograph**. Select **Low Cal**.
- 3. A menu screen appears with the message: "CO2 LOW CAL IN PROGRESS".
- 4. When the unit is finished, a "CALIBRATION COMPLETE" message will appear.
- 5. Press the **MENU/ENTER** (%) key to return to the Capnograph menu, or press the **WAVE/TREND** ( $\frac{\wedge}{1000}$ ) key to exit all menus.

#### Low/High Calibration

#### WARNING! Remove the device from the patient before performing a Low/High Calibration.

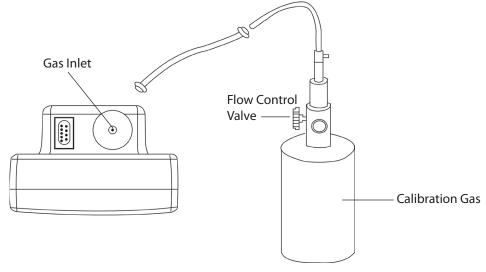


Figure 5-2: Connecting the Calibration Gas

To perform a Low/High Cal do the following:

- 1. Disconnect the patient attachment from the Luer-lock adapter.
- 2. Turn on the device.
- 3. Locate the calibration gas canister.
- 4. Press the **MENU/ENTER** (♥⇒) key. Select **Capnograph**. Select **Low/High Cal** and follow the directions on the display.
- 5. After the message "**PLEASE TURN ON CAL GAS**" appears, quickly open the flow control valve on the calibration gas canister. The valve must be fully opened in less than 30 seconds.
- 6. When the message "CALIBRATION COMPLETE" appears, close the flow control valve of the calibration gas canister, disconnect the calibration test fixture and exit all menus.
- 7. Turn the device off, by pressing the **OFF/ON** % key twice, to ensure the calibration data is saved.

An unsuccessful calibration procedure causes an error message to appear. Operation resumes using the old calibration data. Refer to *Capnograph Messages* in *Chapter 7* of the *Capnograph Operation Manual* for further instructions.

### **Chapter 6: Printer Output**

#### **Printer Setup**

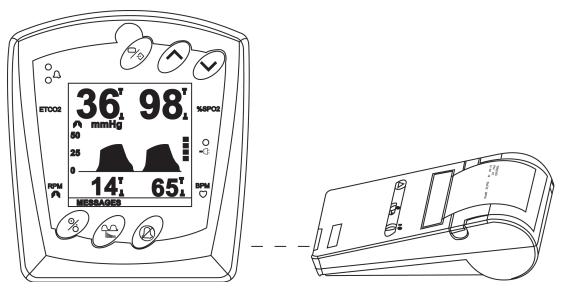


Figure 6-1: Printer Setup

The Capnograph communicates to the Martel MCP8850B printer through the infrared serial port. Align the infrared serial ports as shown in the above illustration. Optimal distance from port to port is 4 – 6 inches. When Capnograph and printer are properly aligned proceed to the Printer menu on the Capnograph.

- WARNING! When connecting to or communicating with this monitor, verify proper operation before clinical use. Refer to the instrument's user manual for full instructions. Accessory equipment connecting to or communicating 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.
- WARNING! IEC 950 approved equipment including the Martel MCP8850B printer must be placed outside of the "patient environment". The patient environment is defined as an area 1.5m (4.92 feet) from the patient.

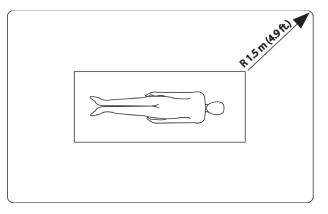


Figure 6-2: Patient Environment

### Printer Menu

The Printer menu allows the user to select a data format for output to the infrared serial port, as well as select the output interval and/or the amount of data to send. This data can be output to a compatible printer.



Figure 6-3: Printer Output Menu, Patient Data

#### **START/STOP**

Select this to enable/disable serial output. If no output is currently in progress, this shows **START**. If output is in progress, this shows **STOP**.

#### **Data Format**

Shows data output format, PATIENT DATA or TREND DATA.

#### Interval

Shows the amount of time between data log outputs.

### **Printer/Output**

The serial output data format and output interval or amount can be changed only if no print output is in progress. To change the data format selection:

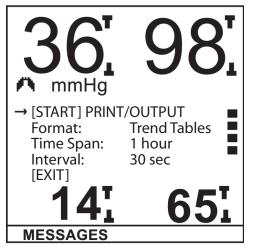


Figure 6-4: Printer Output Menu Trend Tables

Select Printer from the Main Menu. If **[START]** is displayed, then no print output is currently in progress, so proceed with step 2. Otherwise, **[STOP]** is shown and you must select **STOP** to halt the current output before the serial output data settings can be changed.

To change the data format (Patient Data or Trend Tables):

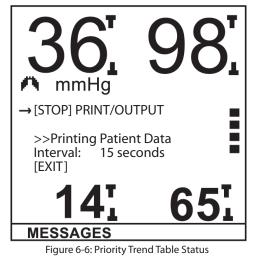
- 1. Use the ARROW (  $\land$  or  $\checkmark$ ) keys to point to the Format item, then press **MENU/ENTER** (%).
- 2. Use the ARROW ( ∧ or ∨) keys to switch between formats. When the format changes, the menu item below it changes.

If Patient Data is selected, the menu item displayed below it is: Interval.



Figure 6-5: Printing Patient Data Status Menu

If Trend Tables is selected, the menu items below are: Time Span and Interval.



3. Press **MENU/ENTER** (%) to accept the selection.

To change the output interval or trend time span:

- 1. Use the ARROW ( ∧ or ∨) keys to point to **Interval** (for Patient Data Format) or **Time Span** (for Trend Tables format), then press **MENU/ENTER** ( ≫).
- 2. Use the ARROW (  $\land$  or  $\checkmark$ ) keys to change the value.
- 3. Press **MENU/ENTER** ( $\Re$ ) to accept the selection.
- 4. When the output format has been set, select **[START]** to enable the serial output. At this point, the **[START]** field will change to **[STOP]**, and the message "**Printing...**" will be displayed in the menu area.
- 5. Select **[EXIT]** or press **WAVE/TREND** ( ) to exit menus. If serial output is in progress, exiting menus will not stop it.

#### Chapter 6: Printer Output

To STOP serial output:

- 1. Select **Printer** from the main menu.
- 2. Select [STOP] (if it is shown).

#### **Output Examples**

#### **Patient Data**

A real-time Patient Data sample is output through the infrared port, one table per output interval. The time interval between tables is selected in the Printer menu. Each line of text in the patient data table ends with a carriage return, line feed.

#### Sample Output (including optional oximetry)

PATIENT DATA		
Sample Interval:	15 se	ecs
Relative Time	00:00	):15
ETCO2	28 m	nHg
inCO2	03 m	nHg
Resp Rate	06 rj	om
SpO2	98 %	3p02
Pulse	74 bj	om
40% N2O/Comp:	No	

#### **Trend Table Data**

Trend data is output in tabular text format, one table per trend data record, starting at the oldest record. The number of records printed depends on the time span selected in the Printer menu. For example, if Time Span = 2 hours, then two hours of accumulated trend data records will be printed.

Each line of text in the trend tables ends with a carriage return, line feed.

Each new block of many trend data records has the following title information:

#### Sample Output (including optional oximetry)

TREND DATA	
Sample Interval:	15 secs
Time Span	1 min
Relative Time	00:50:15
ETCO2	28 mmHg
inCO2	03 mmHg
Resp Rate	06 rpm
SpO2	98 %SpO2
Pulse	74 bpm

### **Chapter 7: Routine Maintenance**

#### **Charging the Battery**

Charge the battery after the monitor is used under battery operation, when the "LOW BATTERY" message is displayed, or after long term storage. Remove the battery from the device. Place the battery in the external charger unit. Verify the green "CHARGING" LED is lit.

After 2.5 hours, the battery is fully charged, indicated by the "CHARGE COMPLETE" LED. To ensure continuos use of the Capnograph, with battery power, the purchase of a second battery is recommended. Please refer to *Chapter 13: Supplies and Accessories* in the *Capnograph Operation Manual* for more information.

CAUTION! The monitor contains a 6 hour Lithium-Ion battery. If the battery fails to hold a charge or otherwise becomes inoperable, the battery should be replaced and the old battery should be disposed of properly. Consult local officials for information about the proper disposal of the Lithium-Ion battery. Smiths Medical PM, Inc. cannot dispose of monitor batteries.

### **Cleaning and Disinfecting**

- CAUTION! Do not immerse the monitor or any of its accessories in liquid. Do not autoclave or ethylene oxide sterilize the monitor or any of its accessories. Unplug the external charger before cleaning or disinfecting the monitor or its accessories.
- CAUTION! Do not allow isopropyl alcohol or water to enter any of the openings in the monitor. Evidence that liquid has been allowed to enter the monitor voids the warranty.
- CAUTION! Before cleaning or disinfecting the Martel MCP8850B printer, unplug the AC adapter, remove the batteries, and remove the paper.
- CAUTION! Should the device become wet, wipe off all moisture and allow sufficient time for drying before operating.

Clean the surfaces of the monitor and the accessories with a soft cloth moistened in a mild soap solution. If disinfecting is required, wipe the surfaces with isopropyl alcohol then wipe with a water moistened soft cloth.

#### CAUTION! Before cleaning the unit, ensure the monitor is off and the mains power cord is disconnected.

# CAUTION! Do not allow liquid to enter the case or submerge any part of the system. Allow components to dry thoroughly before reconnecting system to AC power.

The LCD and all external surfaces may be cleaned with a mild diluted soap solution and a damp soft cloth. Do no use solutions which contain chlorine, ammonia, fluoro-carbons, or hydro-carbons. Do not us abrasive cleaners or high fiber wipes that may scratch the surface. Do not allow cleaners to remain on the system surfaces, wipe off immediately.

CAUTION! Chemicals used in some cleaning agents may cause brittleness of plastic parts. Follow cleaning instructions in this manual.

### **Maintenance Chart**

ITEM	ACTION	INTERVAL
Battery	Charge	When LOW BATTERY message is displayed After continuous use under battery power.
The monitor's surfaces.	Clean or disinfect.	As required.
SpO <sub>2</sub> sensors.	Inspect and change patient site.	Every 4 hours.
	Clean or disinfect.	When attaching a new patient.
Capnograph patient attachment.	Discard the capnograph patient attachment.	When finished monitoring the patient. The capnograph patient attachments are disposable, single- use items. When the patient attachment becomes occluded or has an air leak.
Moisture filter.	Discard and replace the moisture filter.	The moisture filter occludes when it is full.
Capnograph calibration.	Perform a Low/High calibration.	Once every month.
Pneumatic system.	Check pneumatic system for leaks.	After replacing the moisture filter and Capnograph patient attachment. At least once every two weeks.
Calibration gas canister.	Discard and replace the calibration gas canister.	When the gas pressure reading is 20 psi or less as shown on the flow control valve's pressure gauge.

# CAUTION! Follow local governing ordinances and recycling instructions regarding disposal and recycling of device components.

### Long Term Storage

#### WARNING! Remove the device batteries prior to long term storage.

oor
to +75° C (-40 to +167° F)
to 95 %, non-condensing
ne required
re the monitor and accessories in the original packing materials and shipping carton.
t

### Performance and Safety Checks

RECOMMENDED MAINTENANCE	FREQUENCY
General Cleaning	As Needed
Inspect the system, cables, and cords Before Use	
Safety Checks (In Acc. with IEC 601-1)	Annually

#### **Inspecting the System**

Examine the exterior for cleanliness and general physical condition. Ensure the housing is intact, hardware is present and secure, and labeling is legible.

### **Cables and Cords**

Examine the power cord for damage/abuse. Ensure that the prongs of the plug are secure in the casing, and no damage is present in the cord itself.

Inspect all patient cables, leads, and sensors, for general condition.

#### Flow Controller with Gauge - Yearly Flow Rate Test

- 1. Attach the flow controller with gauge to a calibration gas cylinder.
- 2. Attach a 2-foot section of tubing between the flow controller and a flow meter (AALBORG GFM17 or equivalent).
- 3. Turn the knob of the flow controller fully counter-clockwise and read the flow meter. The flow meter should read between 0.255 LPM and 0.345 LPM.

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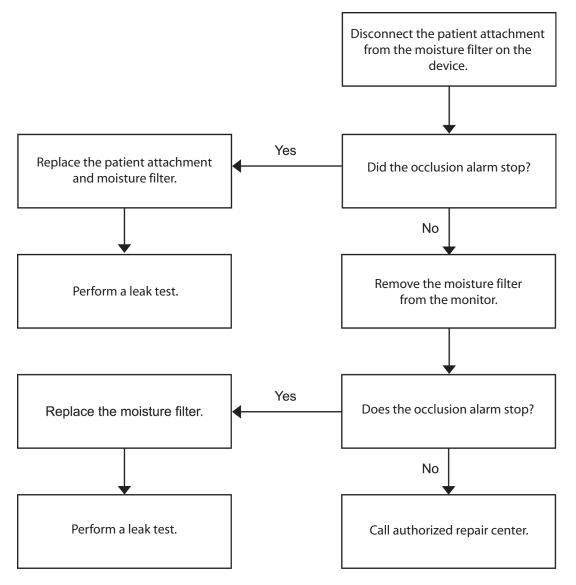
# **Chapter 8: Troubleshooting**

PROBLEM	POSSIBLE CAUSE	SOLUTION
SPO2 SENSOR is displayed.	Sensor not connected to monitor or patient.	Connect the sensor to the patient cable and connect the patient cable to the monitor. Attach the sensor to the patient.
	Sensor improperly positioned on patient.	Reposition the sensor on the patient.
	Incorrect sensor for application.	Choose the correct sensor for the application.
	Defective sensor or patient cable.	Change the sensor or contact Smiths Medical PM, Inc. service department or recharge battery.
Unit operates when connected to external charger, but not on battery power.	Battery shelf life exceeded or battery not charged.	Contact Smiths Medical PM, Inc. service department.
Display does not light.	lf operating on battery, battery may need charging.	Recharge battery.
Green External Power LED not lit.	Battery eliminator not properly seated in unit.	Reseat battery eliminator in unit.
No pulse registering on bargraph.	Sensor or patient cable disconnected from monitor.	Check connections to patient cable and sensor.
	Sensor incorrectly positioned.	Reposition sensor on patient.
	Poor patient perfusion.	Reposition sensor on patient.
	Defective sensor or patient cable.	Try a new sensor or contact Smiths Medical PM, Inc service department.
Pulse rate erratic,	Sensor incorrectly positioned.	Reposition sensor on patient.
intermittent or incorrect.	Poor patient perfusion.	Reposition sensor on patient.
	Patient motion.	Patient must be still for monitor to function properly. Place extremity on a pillow that acts as a "buffer" to motion.
	Ambient light.	Shield with towel.
HIGH CALIBRATION REQUIRED, appears at startup.	Monitor needs calibration.	Contact Smiths Medical PM, Inc. service representative.
NEW CO2 SENSOR, appears at startup.	New CO <sub>2</sub> sensor or new software installed.	Contact Smiths Medical PM, Inc. service representative.
CO2 BENCH ERROR, appears at startup.	The CO <sub>2</sub> Bench is not working.	Contact Smiths Medical PM, Inc. service representative.
SPO2 ERROR, appears at startup.	The Oximeter board has failed.	Contact Smiths Medical PM, Inc. service representative.
User settings lost, reset to default.	User data has been corrupted and reset to factory defaults.	Update any applicable user setting through the menu structure.

# CAUTION! The monitor should be operated from its internal power source if the integrity of the protective earth conductor is in doubt.

### Troubleshooting the Occlusion Low Priority Alarm

Most occlusions are automatically cleared within a minute. If occlusion cycles occur frequently or the occlusion low priority alarm persists, use the following chart to find and repair the problem.



Repairs of Smiths Medical PM, Inc. devices under warranty must be made at authorized repair centers. If the device needs repair, contact your local distributor or Smiths Medical PM, Inc. Service Department. When calling, have the device's model and serial number ready.

Smiths Medical PM, Inc.IN7W22025 Johnson DriveIWaukesha, WI USA 53186-1856I

Phone: (262) 542-3100 Toll-Free: (800) 558-2345 Fax: (262) 542-0718

e-mail address: info.pm@smiths-medical.com

# Chapter 9: Supplies and Accessories

CAT. NO.	DESCRIPTION	QTY
1100	Adapter, Airway, Straight, w/o filter, 12.7 ID x 15 OD (mm)	10/pkg
1101	Cannula + Sample Line, Nasal O <sub>2</sub> , Adult	10/pkg
1102	Cannula + Sample Line, Nasal O <sub>2</sub> , Pediatric	10/pkg
1105	Adapter, Airway, Straight, w/ filter, 12.7 ID x 15 OD (mm)	10/pkg
1114	Adapter, Airway, Dual Port, Straight	10/pkg
1121	Cannula + Sample Line, Oral/Nasal CO <sub>2</sub> , Adult	10/pkg
1123	Sample Line, Oral/Nasal CO <sub>2</sub> , Adult	10/pkg
1124	Sample Line, Oral/Nasal CO <sub>2</sub> , Pediatric	10/pkg
1129	Sample Line, Nasal CO <sub>2</sub> , Adult	10/pkg
1130	Sample Line, Nasal CO $_2$ , Pediatric	10/pkg
1131	Sample Line, Nasal $CO_2$ , Infant	10/pkg
1140	CO <sub>2</sub> Sample Line, Extension, 4.6 m (15 feet)	10/pkg
1151	Adapter, Airway, w/o filter, Pediatric, 12.7 ID x 15 OD (mm)	10/pkg
1152	Adapter, Airway, w/o inter, Pediatric, 12.7 ID x 15 OD (inin) Adapter, Airway, w/ filter, Pediatric, 12.7 ID x 15 OD (inin)	10/pkg
1300	Sensor, Oximetry, Disposable, Adult Finger	10/pkg
1300	Sensor, Oximetry, Disposable, Pediatric Finger, 15-45 kg.	10/box
1302	Sensor: Oximetry, Disposable, Neonate, < 3 kg.	10/box
1302	Sensor, Oximetry, Disposable, Neonate, < 5 kg.	10/box
1606	Simulator, Oximeter/ECG	each
1894		each
1895	Manual, Operation, (Capnocheck <sup>®</sup> II)	each
	Manual, Service, (Capnocheck <sup>®</sup> II)	
3025	Sensor, Oximetry, Wrap, Infant, 3-15 kg	each .
3026	Sensor, Oximetry, Wrap, Neonate, <3 kg	each .
3043	Sensor, Oximetry, Universal 'Y'	each
3044	Sensor, Oximetry, Finger	each
3049	Strips, Adhesive	40/pkg
3078	Sensor, Oximetry, Ear	each
3134	Tape, Attachment, Neonate	50/pkg
3135	Tape, Attachment, Infant	50/pkg
3136	Tape, Attachment, Neonate	100/pkg
3137	Tape, Attachment, Infant	100/pkg
3138	Universal 'Y' Posey Wrap	10/pkg
3178	Pediatric Finger Sensor	each
3311	Cable, Oximetry, 1.5 m (5 feet)	each
3444	Comfort Clip® Finger Sensor, Oximetry	each
5093	ETCO <sub>2</sub> Calibration Gas, (10% CO <sub>2</sub> , 21% O <sub>2</sub> , bal N <sub>2</sub> )	each
8030	Adapter, Airway, Elbow, 15ID/22OD x 15OD (mm)	10/pkg
8044	CO <sub>2</sub> Sample Line, 2.4 m (8 feet)	10/pkg

CAT. NO.	DESCRIPTION	QTY
8061	Calibration Gas Flow Regulator	each
8208	Gas Manifold Filters	10/pkg
8211	CO <sub>2</sub> Sample Line, 1.2 m (4 feet)	10/pkg
8214	Patient Attachment kit (1100, 8211, 8208)	10/pkg
8217	Capnocheck <sup>®</sup> Calibration Kit (5093, 8061, 8223, 8211)	each
8400	Capnograph/Oximetry w/ Battery and Charger	each
8403	Battery Eliminator, 105-125 V, 60 Hz	each
8404	Battery Charger	each
8406	Battery Eliminator, 208-252V, 50/60 Hz	each
8407	Battery Eliminator, 90-220V, 60 Hz	each
8408	Battery, 7.4 V Lithium-Ion Rechargeable	each
8409	Pole Mount Bracket	each
8411	Infrared Printer, Martel MCP8850B	each
8412	Protective Rubber Boot	each
8414	Carrying Case	each
8416	Infrared Printer Paper	4/box

\* The BCI<sup>®</sup> 1302 and 3026 oximetry sensors should not be used on neonatal patients with the Capnograph monitor. Testing has not been conducted for the Capnograph for patients less than 30 days old. These sensors may, however, be used on older patients.

### **Ordering Information**

For ordering information, contact your local distributor or the Smiths Medical PM, Inc. customer service department.

Smiths Medical PM, Inc. N7W22025 Johnson Drive Waukesha, WI USA 53186-1856 Phone: (262) 542-3100 Toll-Free: (800) 558-2345 Fax: (262) 542-0718

e-mail address: info.pm@smiths-medical.com

# **Chapter 10: Specifications**

### Capnograph

Display:	LCD, with electroluminescent (EL) back light 160 X 160 pixels; 38.4 cm2, 62 x 62 mm
Measurement:	Non-Dispersive IR absorption
Calibration:	Manual 2 point.
Measurement Range:	0-10% CO <sub>2</sub> STPD (standard temperature and pressure dry)
Display Range:	0-100 mmHg; 0-13.3 kPa; 0-10% CO <sub>2</sub>
Display Update Rate:	Waveform data updates at 24 Hz using a sliding erase bar to pro-vide sweep speeds. Numerical data and messages are updated at 1 Hz. Sp0 <sub>2</sub> pulse strength bar and the breath indicator update at 60 Hz.
Accuracy:*	± 2mmHg or 4% of reading, whichever is greater
Stability:	≤ 0.3% (vol) CO <sub>2</sub> /24hrs
Rise Time:	325ms (average)
Delay Time:	2.140s (average)
System Response Time:	2.465s (average)
Time from power on to accurate readings:	3 minutes (typical)
N2O Compensation:	selectable 40% (default = OFF)
Averaging:	4 breath average
Flow Rate:	120 ± 20 ml/min

\* Accuracy specification for respiration rates less than 50 breaths per minute.  $ETCO_2$  specification for 51-80 breaths per minute is -10% of reading and for 81-150 breaths per minute is -20% of the reading.

### **Respiration Rate**

Range:	0-150 breaths/min
Accuracy:	±1 bpm
Averaging:	4 breath average
Display Update Rate:	1 Hz for Respiration value

# SpO<sub>2</sub> (optional)

Range:	0-100% SpO <sub>2</sub> (functional)
Accuracy:	± 2 at 70-100% SpO <sub>2</sub> ± 3 at 50-69% SpO <sub>2</sub>
Averaging: <sup>1</sup>	8 beats
Pulse Tone:	Pitch corresponds to SpO <sub>2</sub> value. Value adjustable or OFF.
Display Update Rate:	1Hz for SpO <sub>2</sub> value, 60Hz for waveform
Sensor:	Red 660nm, 2.0 mW Infrared 905 nm, 2.0 - 2.4 mW
Calibration:	Factory calibrated over 50% to 100% using human blood samples to functional saturation. Test methods available upon request. No in-service calibration required.

<sup>1</sup> Because pulse oximeter measurements are statistically distributed, only about two-thirds of pulse oximeter equipment can be expected to fall within the A<sub>RMS</sub> of the value measured by the CO-oximeter. The 8400 Capnocheck<sup>®</sup> II has been validated in human desaturation studies on 10 adult volunteers that did not have health problems and were non-smokers. The study was conducted at oxygen concentrations evenly distributed over an SaO<sub>2</sub> range of 50-100%.

### Peripheral Pulse Rate (optional)

Range:	30-254 bpm
Accuracy:	$\pm 2$ bpm or 2%, whichever is greater, at 30 to 254 bpm
Averaging:	8 seconds
Display Update Rate:	1Hz

### **Pulse Strength (optional)**

NOT proportional to pulse volume!		
Range:	30-254 bpm, indicates logarithmic strength of patient's pulse	
Display:	8 segment bargraph	
Display Update Rate:	60Hz	

## **Alarm Limits Ranges**

ETCO <sub>2</sub>				
High:	0-100 mmHg (1 mmHg steps), and OFF 0-13.3 kPa (0.1 kPa steps), and OFF 0-10.0% CO <sub>2</sub> (0.1% steps), and OFF			
Low:	0-100 mmHg (1 mmHg steps), and OFF			
Factory Defaults:	High = 60 mmHg Low = 20 mmHg			
Resp Rate				
High:	5-150 bpm (1 bpm steps), and OFF			
Low:	5-150 bpm (1 bpm steps), and OFF			
Factory Defaults:	High = 35 bpm Low = 5 bpm			
Inspired CO <sub>2</sub>				
High:	0-100 mmHg (1 mmHg steps), and OFF 0-13.3 kPa, 0.1 kPa steps, and OFF 0-10.0% CO <sub>2</sub> , 0.1% steps, and OFF			
Factory Default:	High = 8 mmHg			
Pulse Rate				
High:	30-254 bpm (1 bpm steps), and OFF			
Low:	30-254 bpm (1 bpm steps), and OFF			
Factory Defaults:	High = 150 bpm Low = 45 bpm			
SpO <sub>2</sub>				
High:	50-100% (1% steps), and OFF			
Low:	50-100% (1% steps), and OFF			
Factory Defaults:	High = OFF Low = 85%			
Volume:	45dBA - 85dBA (adjustable) at 1 meter distance			
NOTE! User set alarm limits will be retained through power cycles.				

### Serial Output

Infrared Port compatible with MCP8850B Printer or similar device.		
Data Format:	Non-standard format ~ 500 baud	
Options:	Text only, no graphics. Patient data log or trend tables	

#### Chapter 10: Specifications

### Power

AC Power (Optional) See Chapter 13: Supplies and Accessories			
Battery Charger:	MoliEnergy Agency Approvals pending		
Battery:	LI+ (lithium-lon), 7.4 VDC Replaceable internal rechargeable. Fully charged continuous use life of approximately 6 hours. Maximum full-capacity charging time is 2.5 hours		
Battery Disposal:	The battery must be disposed of properly. For more information contact your local authorities.		

## Physical

#### Dimensions

Width:	111 mm (4.38 inches)	
Height:	127 mm (5 inches)	
Depth:	pth: 73.7 mm (2.9 inches)	
Weight:	0.63 kg (22 ounces)	

### Environment

Temperature	
Operation:	0 to 50° C (32 to 122° F)
Storage:	-40 to +75° C (-40 to +167° F)
Relative Humidity	
Operation:	15 to 95% (non-condensing)
Storage:	10 to 95% (non-condensing)
EMC:	As per the most recent FDA guidelines for Respiratory and Oximetry devices, and EN60601-1-2.
Atmospheric Pressure:	525 mmHg (10,000 feet above sea level) to 795 mmHg (1250 feet below sea level)

# Appendix

### Parts Lists, Assembly Drawings and Schematics

Assemblies, drawing, schematics, and component information not contained in this manual are available upon request to Smiths Medical PM, Inc.

NUMBER	DESCRPTION	ITEM	NUMBER OF PAGES
20650A1	F/Asm Drawing	A-1	4
20650A1	F/Asm Bill of Materials	A-2	2
20652B1	Asm Drawing Main Board	A-3	1
20652B1	Parts List Main Board	A-4	4
20652S1	Main Board Schematic	A-5	5
20656B1	Asm Drawing Battery Interface	A-6	1
20656B1	Parts List Battery Interface	A-7	1
20656S1	Schematic Battery Interface	A-8	1
20681A1	Asm Main/Display/SpO2 PWB	A-9	2
20681A1	Bill of Materials Main/Display/SpO2 PWB	A-10	1
20682A1, A2, A3	Asm Battery Interfaces 110V, 220V and 90V	A-11	1
20682A1	BOM for 110V Asm Battery Interface	A-12	1
20682A2	BOM for 220V Asm Battery Interface	A-13	1
20682A3	BOM for 90V Asm Battery Interface	A-14	1
71202B1	AC Power Supply 105V-125V 60Hz	A-15	2
71202B2	AC Power Supply 208V-252V 50/60Hz	A-16	3
71202B3	AC Power Supply 90V	A-17	2
71552B1	PWB Asm Main BC SpO2	A-18	1
71552B1	Parts List Business Card SpO2	A-19	3
71552S1	Schematic Main SpO2	A-20	3

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