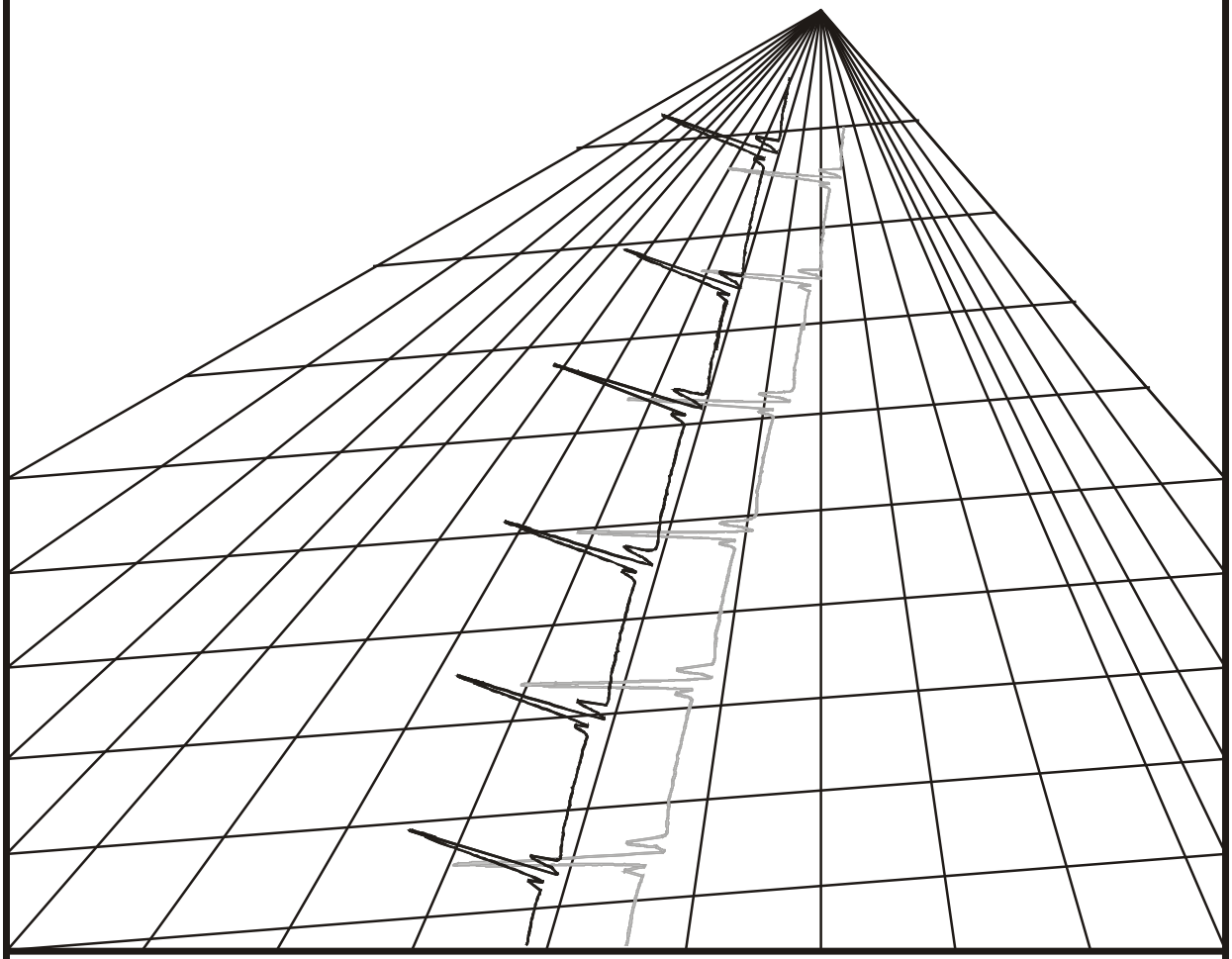
IVY BIOMEDICAL SYSTEMS, INC.

Vital-Guard *450C*

Patient Monitor

with Masimo SET® SpO_2



2684-01-20

Operation and Maintenance Manual

User Responsibility

This product will perform in conformity with the description thereof contained in this Operation and Maintenance Manual and accompanying labels and/or inserts, when assembled, operated, maintained and repaired in accordance with the instructions provided. This product must be checked periodically. A defective Product should not be used. Parts that are broken, missing, plainly worn, distorted or contaminated should be replaced immediately. Should such repair or replacement become necessary, IVY Biomedical Systems, Inc. recommends that a telephone call or written request for service advice be made to IVY Biomedical Systems, Inc. Service Department. This product or any of its parts should not be repaired other than in accordance with instructions provided by IVY Biomedical Systems, Inc. trained personnel. The product must not be altered without the prior written approval of IVY Biomedical Systems, Inc. Quality Assurance Department. The user of this Product shall have the sole responsibility for any malfunction, which results from improper use, faulty maintenance, improper repair, damage or alteration by anyone other than IVY Biomedical Systems, Inc.

CAUTION: US Federal law restricts this device to sale by or on the order of a licensed medical practitioner.

Ivy Biomedical Systems, Inc. has declared that this product conforms with the Eurpean Council Directive 93/42/EEC Medical Device Directive when its used in accordance with the instructions provided in the Operation and Maintenance Manual.

CE 0413

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Declaration of Conformity

Manufacturer:	Ivy Biomedical Systems, Inc. 11 Business Park Drive Branford, CT 06405
Authorized Representative:	Cavendish Scott Ltd. Starlings Bridge, Nightingale Road Hitchin, Herts, SG5 1FW, England
Type of Equipment:	Physiological Monitors
Models:	450C

We, Ivy Biomedical Systems, Inc., hereby declare that the devices mentioned above comply with the Swedish National Board of Health and Welfare Regulation and guidelines on medical devices LVFS 2003:11 (M) 28 October 1994 – transposing European Medical Devices Directive 93/42/EEC.

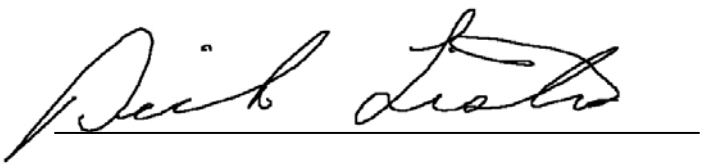
Date of Validity: March 30, 2010

Classification: IIb According to rule No. 10

Conformity Assessment Procedure: Annex II

Notified Body: Intertek SEMKO AB Notified Body No. 0413

Name of Authorized Signatory: Dick Listro
Position held in Company: Director of Regulatory

Signature 

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WARRANTY

All products manufactured by Ivy Biomedical Systems, Inc. are warranted to be free from defects in material and workmanship and to operate within published specifications, under normal use, for a period of one year from date of original shipment.

All accessories supplied by Ivy Biomedical Systems, Inc. are warranted to be free from defects in material and workmanship and to operate within published specifications, under normal use, for a period of 90 days from date of original shipment.

If an examination by Ivy Biomedical Systems, Inc. discloses such products or component parts to have been defective, then our obligation is limited to repair or replacement (at our option). Fuses and batteries are not covered under this warranty.

If products need to be returned to the manufacturer for repair or examination contact customer service personnel at IVY Biomedical Systems, Inc. to obtain the Return Authorization Number (RMA) and proper packing instructions.

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INTRODUCTION

This manual is to provide information on the correct use of the Vital-Guard *450C* patient monitor. It is up to the user to ensure that any applicable regulations regarding the installation and operation of the monitor are observed.

The Information regarding circuit diagrams, board layouts and replacement parts is contained in the Operation and Maintenance Manual. For instructions on how to obtain the Operation Manual or the Operation and Maintenance Manual please contact customer service personnel at IVY Biomedical Systems, Inc.

The model 450C is to be operated by qualified personnel only.

Using This Manual

We recommend that you read this entire manual before operating the equipment. This manual is written to include all parameters for a fully configured monitor. If the configuration of your monitor does not include all parameters, menu selections and display data for those parameters will not appear on your monitor.

Use the Monitor Description section for general descriptions of controls and displays. For details on monitoring each parameter, refer to the section of the manual dealing with the appropriate parameter.

> NOTE: If the monitor beeps when you press a key, it indicates an invalid selection for the current mode or function.

Boldface type is used in text to refer to the labeling on user controls. Special brackets [ ] surround menu selections used with the programmable keys.

Manufacturer's Responsibility

The manufacturer of this equipment is responsible for the effects on safety, reliability, and performance of the equipment only if:

- Assembly operations, extensions, re-adjustments, or repairs are carried out by persons authorized by the manufacturer
- The electrical installation complies with all applicable regulations
- The equipment is used in accordance with the instructions in this manual

Incorrect operation or failure of the user to maintain the monitor in accordance with proper maintenance procedures relieves the manufacturer or his agent from all responsibility for consequent non-compliance, damage, or injury.

For technical and service information, please refer to the Vital-Guard *450C* Operation and Maintenance Manual or contact:

Ivy Biomedical Systems, Inc.
11 Business Park Drive
Branford, Connecticut 06405
(203) 481-4183 or (800) 247-4614
e-mail: techline@ivybiomedical.com

This manual explains how to set up and use the Model 450C. Important safety information relating to general use of the pulse oximeter appears in this manual. Other important safety information is located throughout the manual where appropriate. READ THE ENTIRE SAFETY INFORMATION SECTION BEFORE YOU OPERATE THE MONITOR.

SAFETY

Electrical

This product is intended to be operated from a mains power source of nominally 100 to 230 V ~, 47-63 Hz, or from its internal battery.

WARNING: To prevent electrical hazards to all personnel, this monitor must be properly grounded. Connect the monitor only to a three-wire, grounded, hospital grade receptacle. The three-conductor plug must be inserted into a properly wired three-wire receptacle; if a three-wire receptacle is not available, a qualified electrician must install one in accordance with the governing electric code.

WARNING: Do not under any circumstances remove grounding conductor from the power plug.

WARNING: The power cable supplied with this equipment provides for this protection. Do not attempt to defeat this protection by modifying the cable or by using ungrounded adapters or extension cables. The power cord and plug must be intact and undamaged. To disconnect the equipment from the mains power unplug the power cord.

WARNING: Do not connect to an electrical outlet controlled by a wall switch or dimmer.

WARNING: If there any doubt about the integrity of the protective earth conductor arrangement, operate the monitor on internal battery power until the AC power source protective conductor is fully functional.

WARNING: Do not place the monitor in any position that may cause it to fall on the patient. Do not lift the monitor by the power supply cord or patient cable, use only the handle on the monitor.

WARNING: Electric shock hazard! Do not remove covers or panels. Refer service to qualified service personnel.

WARNING: To avoid electrical shock, disconnect the monitor from its power source before changing fuses. Replace fuses only with same type and rating (1.6ASB, Metric 5x20mm, 250V).

WARNING: Do not clean monitor while it is on and/or plugged into a power source.

WARNING: If unit is accidentally wet, discontinue use until dry and then test unit for proper operation before reuse on patient.

WARNING: This unit uses a common isolation path for the ECG leads. Do not connect any non-isolated accessories to the ECG input when connected to a patient, as this may compromise the safety of the unit. When attached to other devices, insure that the total chassis leakage currents of all units do not exceed 300 μA.

Explosion

DANGER: Explosion hazard! Do not use this equipment in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environment or nitrous oxide.

Patient Connections

Patient connections are electrically isolated. For all connections use isolated probes. Don't let patient connections contact other conductive parts, including earth. See instructions for patient connections in this manual.

Carefully route patient cables to reduce the possibility of patient entanglement or strangulation.

Leakage current is limited internally by this monitor to less than 10 μA. However, always consider cumulative leakage current that can be caused by other equipment used on the patient at the same time as this monitor.

To ensure that the leakage current protection remains within the specifications, use only the patient cables specified in this manual. This monitor is supplied with protected lead wires. *Do not use* cables and leads with unprotected lead wires having exposed conductors at the cable end. Unprotected lead wires and cables may pose an unreasonable risk of adverse health consequences or death.

If an alarm condition occurs while the alarms are set to off, the only alarm indication will be visual displays and symbols related to the alarm condition.

MRI

The model 450C should not be used within the magnetic field during Magnetic Resonance Imaging.

Pacemakers

Rate meters might continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely on rate meter alarms. *Keep pacemaker patients under close surveillance.*

Electrosurgery

To avoid the potential of electrosurgery burns at monitoring sites, ensure proper connection of the electrosurgery return circuit as described by manufacturer's instructions. If improperly connected, some electrosurgery units might allow energy to return through the ECG electrodes, SpO2 sensors, Pressure Transducers, EtCO2 sensors, and Temperature probes. To further reduce the potential of burns, locate the SpO2 sensors, Pressure Transducers, EtCO2 sensors, and Temperature probes as described in the manufacturer's instructions.

Defibrillation Protection

This equipment is protected against 360 J discharge and electrosurgery potentials. The monitor is internally protected to limit current through the electrodes to prevent injury to the patient and damage to the equipment as long as the defibrillator is used in conformance with the manufacturer's instructions.

EMC

This equipment has been certified to be protected to emissions and immunity according to IEC-60601-1-2.

Electromagnetic Compatibility IEC 60601-1-2:2001

CAUTION: Medical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Operation Manual.

CAUTION: Portable and mobile RF communications equipment can affect medical electrical equipment.

WARNING: The model 450C should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Model 450C should be observed to verify normal operation in the configuration in which it will used.

Accessories

WARNING: The use of accessories other than those specified below may result in increased emissions or decreased immunity of the equipment.

Part Number	Description
590170	Three lead patient cable
590162	Set of three lead wires
590167	Five lead patient cable
590168	Set of five lead wires
590198	Set of three lead wires for prewired electrodes
590317	Low noise three lead patient cable
590318	Set of three radiotranslucent lead wires
590323	Low noise three lead patient cable with 1kohm resistors.

The minimum amplitude or value patient physiological signal is 0.5 mV (AAMI EC-13 3.2.6.1).

WARNING: The use of the Model 450C below the following amplitude values may cause inaccurate results:

Guidance and manufacturer's declaration – Electromagnetic emissions		
The Model 450C is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 450C should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Model 450C uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Model 450C is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – Electromagnetic immunity			
The Model 450C is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 450C should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8kV air	±6 kV contact ±8kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±250V differential mode ±2 kV common mode	Remove equipment that can cause electrical disturbance from the vicinity of the input/output cables.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec cycle	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Model 450C requires continued operation during power mains interruptions, it is recommended that the Model 450C be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	Not applicable

Guidance and manufacturer's declaration – Electromagnetic immunity			
The Model 450C is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 450C should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Model 450C, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{p}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{p}$ 80 MHz to 800 MHz $d = 2.3\sqrt{p}$ 800 MHz to 2.5 GHz Where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b] Interference may occur in the vicinity of the equipment marked with the following symbol: 
NOTE 1 – At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 – These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the Model 450C is used exceeds the applicable RF compliance level above, the Model 450C should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model 450C. [b] Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.			

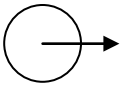
Description of Warning Labels

Attention, consult ACCOMPANYING DOCUMENTS before attempting to change power supply selection or carry out interconnections. Equipment connected should comply with IEC-60601-1 or IEC-950 with configuration to IEC-60601-1-1.

Type CF applied part, Defibrillator proof.

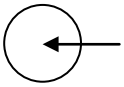
Equipotential earth connector adjacent to this symbol.

Fuse type/rating.



Output signal.

ON



Input signal.

Stand By (STBY)

~

Alternate Current (AC)

Type CF applied part.

WEEE Compliance

For monitors used in Australia

For continued Defibrillation protection and proper Respiration monitoring use only patient cables with 1kΩ series resistors. It is important to use only patient cables with 1kΩ series resistors because the respiration circuit is tuned to operate with series resistors.

For 3-lead configuration monitors, use 3-lead patient cable with 1kΩ series resistors. Ivy reorder no. 590197.
For 5-lead configuration monitors, use 5-lead patient cable with 1kΩ series resistors. Ivy reorder no. 590207.

MONITOR DESCRIPTION

The Model 450C Patient Monitor is a color four-trace *adult, pediatric, or neonatal* monitor for:

ECG
Heart Rate
Respiration - Impedance
EtCO2
Two Invasive Pressures
Two Temperatures
Non-Invasive Blood Pressure (NIBP)
Pulse Oximetry

The Model 450C is available in several configurations, therefore, not all parameters are included in all monitors.

The use of the Model 450C is restricted to one patient at a time. The monitor is intended for use in emergency room, recovery room, intensive care, and surgical applications and transport with 2.5 hours battery operation.

The Model 450C is suitable for use in presence of electrosurgery.

The Model 450C is not intended for use with any other physiological monitoring unit.

An optional integral recorder is available. Recorder settings are made through the monitor menus. Battery operation consists of two rechargeable lead acid cells.

The display has four traces available and alphanumeric displays for data, alarms, and user information, such as menus. The monitor automatically senses which devices are connected and acquires and displays data for the parameters being used. Data for parameters not being used is not displayed. Areas for display of those parameters are left blank.

Classification (in accordance with IEC-60601-1)

Protection against electric shock:	Class 1 and internally power equipment
Degree of protection against electric shock:	Type CF applied part. Defibrillator proof: ECG Type CF applied part: SpO_2, IBP, Temperature, NIBP, & $EtCO_2$.
Degree of protection against harmful ingress of water:	Ordinary equipment IPX0 per IEC-60529
Methods of Maintenance and Cleaning:	See page 72
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide:	Equipment not suitable for use in the presence of a flammable anesthetic mixture
Mode of operation:	Continuous

Specifications

ECG

Lead Selection:	Standard Three-Lead:	LI, LII, LIII,
	Five-Lead Option:	LI, LII, LIII, aVR, aVL, aVF, V
ECG Amplitud range:	1 to 100 mm/mv	
Patient Cable:	6-Pin AAMI Standard	
Isolation:	Isolated from ground related circuits by ≥4 kV rms, 5.5 kV peak	
CMRR:	≥90 dB with patient cable and 51 kΩ/47 nF imbalance	
Input Impedance:	≥20 MΩ at 10 Hz with patient cable	
Frequency Response Display, at 50 mm/sec:	Filtered:	0.5 to 35 Hz
	Diagnostic:	0.05 to 100 Hz
Frequency Response X1000 Output:	Filtered:	0.5 to 35 Hz
	Diagnostic:	0.05 to 100 Hz
Input Bias Current:	Any lead configuration <200 nA dc maximum	
Electrode Offset Potential:	± 0.5 V	
Noise:	<20 μV peak-to-peak, referred to the input with all leads connected through 51 kΩ/47 nF to ground	
Defibrillator Protection:	Protected against 360 J discharge.	
Leakage Current:	<10 μA at 120 V ~, 60 Hz	
Electrosurgical Interference Protection:	Standard	
Lead Fault Detection:	Lead fault detection in any lead configuration with any of the leads open	

NOTE: The Phase Delay from patient electrode to rear panel outputs is < 3ms

Cardiotach

Range:	15 to 300 bpm	
Accuracy:	±1%	
Resolution:	1 bpm	
Sensitivity:	Adult:	300 μV peak
	Neonate:	100 μV peak
Pacer Rejection Width:	0.1 to 2 ms at ±2 to ±700 mV	
Tall T Wave Rejection:	Rejects T waves ≤R wave	

Temperature (Two Channels)

Thermistor:	YSI Series 400 or equivalent
Range:	19°C to 45°C
Accuracy:	±0.1°C from 25°C to 40°C
Resolution:	0.1°C
Isolation:	Isolated from ground related circuits by ≥4 kV rms, 5.5 kV peak
Leakage:	<10 μA at 120 V ~, 60 Hz

Respiration

Excitation Current:	<400 μA rms	
Excitation Frequency:	57 kHz	
Maximum Electrode Impedance:	4 kΩ	
Size Adjustment:	Manual	
Respirotach Range:	Neonate:	4 to 150 br/min
	Adult:	4 to 60 br/min
Sensitivity Range:	Neonate:	0.1 to 10 Ω, 4 to 150 br/min
	Adult:	0.3 to 10 Ω, 4 to 60 br/min
Pace Pulse Rejection Width:	0.1 to 2 ms at ±2 to ±700 mV	

End Tidal CO_2

Measurement Range:	0.0 to 100.0 Torr	
Reporting Range:	–5.0 to 120.0 Torr	
Resolution:	0.1 Torr (0.01%)	
Bias:	0.0 to 40.0 Torr:	±2.0 Torr Abs
	40.1 to 100.0 Torr:	±5.0% Relative
Precision:	0.0 to 40.0 Torr	<0.5 Torr (RMS)
	40.1 to 100 Torr	<1.0 Torr (RMS)
CO_2 Compensation:	Local Barometric Pressure:	500 to 850 Torr (in whole units)
	N_2O	0 to 100% (in whole units)
	O_2	0 to 100% (in whole units)

MASIMO SET® Pulse Oximetry

Range:

Saturation (%SpO2)	1% - 100%
Pulse Rate (bpm)	25 - 240

Accuracy:

Saturation (%SpO2) – During no motion conditions

Adults	70% - 100% ± 2 digits
	0% - 69% unspecified
Neonates	70% - 100% ± 3 digits

Saturation (%SpO2) – During motion conditions

Adults	70% - 100% ± 3 digits
	0% - 69% unspecified

Pulse (bpm) – During no motion conditions

25 to 240 ± 3 digits

Pulse (bpm) – During motion conditions

25 to 240 ± 5 digits

Resolution:

Saturation (%SpO2)	1%
Pulse Rate (bpm)	1

Non-Invasive Blood Pressure

Measurement Technique: Oscillometric method determines mean arterial pressure (MAP), systolic, and diastolic pressure.

Resolution: 1 mmHg

Measuring Range:

	Adult (mmHg)	**Neonatal (mmHg)**
Systolic	60–250	40–130
Mean	45–235	35–105
Diastolic	40–220	20– 90
Pulse Rate	30 –180	30 –240

Accuracy: Over the blood pressure measurement range stated above, for systolic and diastolic pressures treated separately, the mean difference of the paired measurement of the test system and the comparison system shall be ±5mmHg or less, with a standard deviation of 8mmHg or less.

Inflation speed: At sea level <10 seconds.

Maximum leak rate: 5 mmHg/3 min.

Over pressure protector:	Adult/Child	300mmHg
(Maximum cuff pressure)	Neonate	150mmHg

Modes:	**Auto:** Measurements are automatically repeated at timed programmed intervals of 1, 2, 3, 4, 5, 10, 15, 20, 30, or 60 minutes **Stat:** A series of consecutive measurements; the series lasts for 5 minutes. **Manual:** A single reading each time **START** is pressed.
Alarms:	High and low pressure alarms derived from the NIBP systolic, diastolic, or mean

Invasive Pressure (Two Channels)

Frequency Response:	dc to 12 Hz
Input Impedance:	500 kΩ
Transducer Sensitivity:	50 μV/V/cm Hg
Excitation Voltage:	+5 V dc
Zero:	Auto pushbutton, ±150 mmHg
Drift:	0.1 mmHg/^{o}C
Accuracy:	±2% of reading or ±1 mmHg, whichever is greater
Isolation:	Isolated from ground related circuits by ≥4 kV rms, 5.5 kV peak
Test Waveform:	150/50 mmHg

NOTE: Refer to the manufacturer's documentation for technical specifications on any particular pressure transducer.

Alarms

Heart Rate:	High and Low: 15 to 300 bpm in 5 bpm increments
SpO_2:	High: 70 to 99% in 1% increments Low: 50 to 95% in 1% increments
Asystole:	R to R interval >6 seconds
No Pulse:	When triggering from pleth or invasive pressure, interval >6 seconds
Lead Off:	Detached lead or offset potential ≥0.5 V
Check Leads:	Electrode impedance is >4 kΩ
Coincidence:	When QRS and respiration triggers are synchronized for eight consecutive events
Apnea:	Absence of detectable respiration activity for 5, 10, 15,, or 20 seconds

MONITOR DESCRIPTION

Alarms

Resp Rate:	High and Low: 5 to 150 br/min in 5 br/min increments
Invasive Pressure:	High and low; systolic, diastolic, or mean: -40 to 300 mmHg in 2 mmHg increments
NIBP:	High and low; systolic, diastolic, or mean: 10 to 300 mmHg in 2 mmHg increments

For additional NIBP alarm conditions, see the NIBP Monitoring section of this manual.

Trends

NIBP:	Last 200 readings, tabular
Cardiorespirogram:	Up to 4 minutes beat-to-beat heart rate and respiration
Trend Waveforms:	Up to 24 hours of heart rate, respiration rate, SpO_2, and invasive pressure
Review Trend:	6 hour view: Stored the last 24 hours of heart rate, respiration rate, SpO2 and IBP. Six hours of data are displayed per window. (1 pixel = 1 minute). 30 minute view: Stored the last 24 hours of heart rate, respiration rate, SpO_2 and IBP. Thirty minutes of data are displayed per window. (1 pixel = 5 seconds).

Real Time Clock

Resolution:	1 minute
Display:	24 hours
Power Requirement:	The real time clock keeps time if the monitor has power or not. The clock is powered by a dedicated battery whose life is minimum 4 years at a temperature of 25^{o}C

Test Mode

ECG:	1 mV/100 ms @ 70 bpm
Respiration:	70 br/min, coincidence check
Invasive Pressures:	150/50 mmHg
Temperatures:	40^{o}C

Display

Type:	Active Matrix TFT Color LCD	
Trace:	Four Traces, moving bar	
Screen size (viewing area):	Height:	158.4 mm
	Width:	211.2 mm

Display

Sweep Speed:	6.25, 12.5, 25, 50 mm/s	
Character Size:	Large:	13x8 mm
	Small:	4x3 mm

Recorder

Writing Method:	Direct Thermal
Number of Traces:	2
Modes:	Direct - Manual Recording Timed - Print button initiates a 30 second recording Delay - Recorder is activated by an alarm Auto - Parameters to be printed are selected based on the alarm CRG - Prints Cardiorespirogram Remote - Allows activation of a remote recorder
Paper Speeds:	1 mm/s in CRG mode, 6.25, 12.5, 25 and 50 mm/s
Trends:	Printed as selected for the display NIBP tabular - prints up to 200 measurements as shown on the display
Resolution:	Vertical - 200 dots/in. Horizontal - 600 dots/in. at ≤25 mm/s 400 dots/in. at >25 mm/s
Frequency Response:	>100 Hz at 50 mm/s
Data Rate:	400 samples/s/trace

Mechanical

Size:	Height:	11.0 in. (28.0 cm)
	Width:	11.1 in. (28.2 cm)
	Depth:	7.5 in. (19.1 cm)
Weight:	Basic unit: 12.8 lbs. (5.8 kgs.)	

Environmental

Operating Temperature Range:	15°C to 35°C
Storage Temperature Range:	-5°C to 55°C
Relative Humidity:	0-90% non-condensing

Power Requirements

Voltage Input:	100 - 230 V ~; 47 - 63 Hz, +10% –15%	
Fuses Type and Rating:	1.6ASB, Metric 5x20mm, 250V	
Maximum ac Power Consumption:	145 VA	
Battery:	Run Time:	2.5 hours – (NIBP measurement every 15 minutes and 30-second recorder print-out every 30 minutes)
	Charge Time:	<12 hours
	Type:	Replaceable sealed gel cell, DOT and IATA approved

Controls and Indicators

Setup Keys

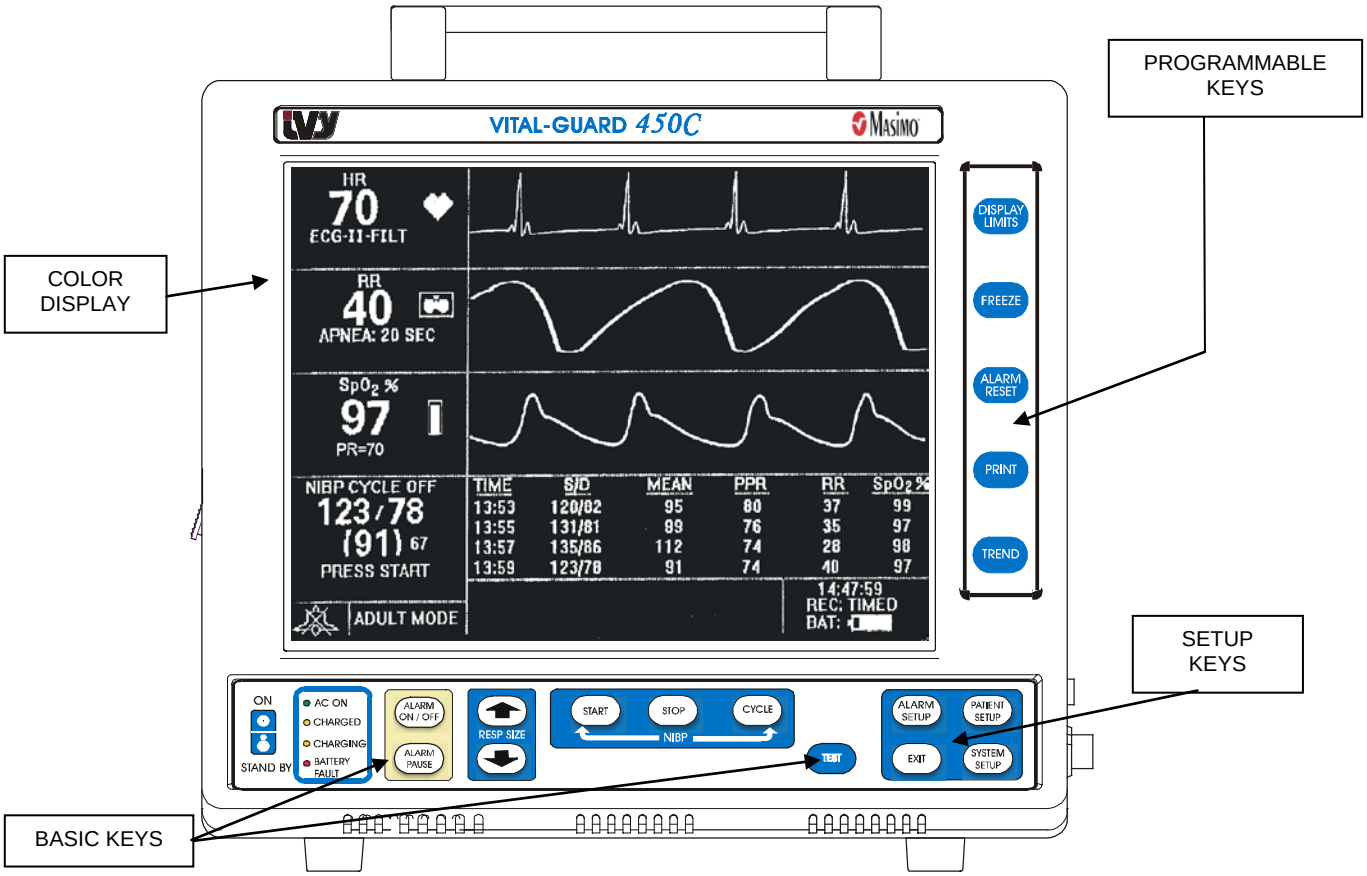
PATIENT SETUP Causes menu to be displayed for settings involving the parameters.

SYSTEM SETUP Displays menus for general settings, such as display and recorder setup, adult/neonatal mode, and audio and clock settings.

ALARM SETUP To set limits for all parameters

EXIT To leave a menu and return to the normal display.

See the Menu Structure section of this manual for a description of the menus.



Basic Keys

TEST

Generates a 1 mV pulse at 70 bpm, respiration signal at 70 br/min, (coincidence check), invasive blood pressures at 150/50, and temperatures at 40°C displayed on the screen and sent to the rear panel. This key is used to verify that the monitor is functioning correctly. In TEST, heart rate is always computed from the generated ECG.

ON/OFF

Turns the alarm audio on and off. When off, the **ALARMS OFF** tag is displayed on the screen.

ALARM PAUSE

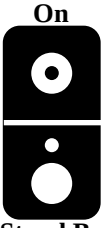
Disables the audible and visual alarms for a two-minute period to allow the operator to perform procedures that would otherwise set off the alarms. This avoids the problem of turning off the alarms and forgetting to turn them back on. A message on the screen indicates when this function is active. Press the **ALARM PAUSE** key again to return the alarms to normal before the two minutes have expired.

Respiration Size

The up and down arrows control the relative size of the respiration signal. Size ranges are from 0 to 100%. This controls both the display size and the trigger sensitivity.

NOTE: If the respiration size is set for a very sensitive range, cardiac artifact can generate false triggers, causing a coincidence alarm.

On



Stand By

When the monitor is either plugged into an AC power source or operating on batteries, the switch toggles from Stand By (off position) to ON providing power to the monitor's electronic circuits. The monitor must be connected to an AC source to be able to charge the internal batteries.
NOTE: To disconnect the monitor from the mains power unplug the power cord.

NIBP Control Keys

START

Starts a single non-invasive blood pressure measurement in cycle off (manual mode) or repetitive measurements in cycle mode or stat mode. Measurements in any mode can be canceled by pressing **STOP.**

STOP

Stops any non-invasive blood pressure measurements in cycle off (manual mode), automatic mode, or stat mode and cancels automatic or stat mode.

CYCLE

Selects the NIBP mode of operation. Selections are: automatic cycle mode, stat mode or cycle off (manual mode). In the automatic cycle mode inflation intervals of 1, 2, 3, 4, 5, 10, 15, 20, 30 or 60 minutes can be selected.

Programmable keys

Each of the keys to the right of the display has a normal function, printed on the key, and several menu functions displayed on the screen in the setup mode. The normal functions are described below. Menu functions are described in the menu structure section of this manual.

Displays the current alarm limit settings. Press **DISPLAY LIMITS** again to return to normal display.

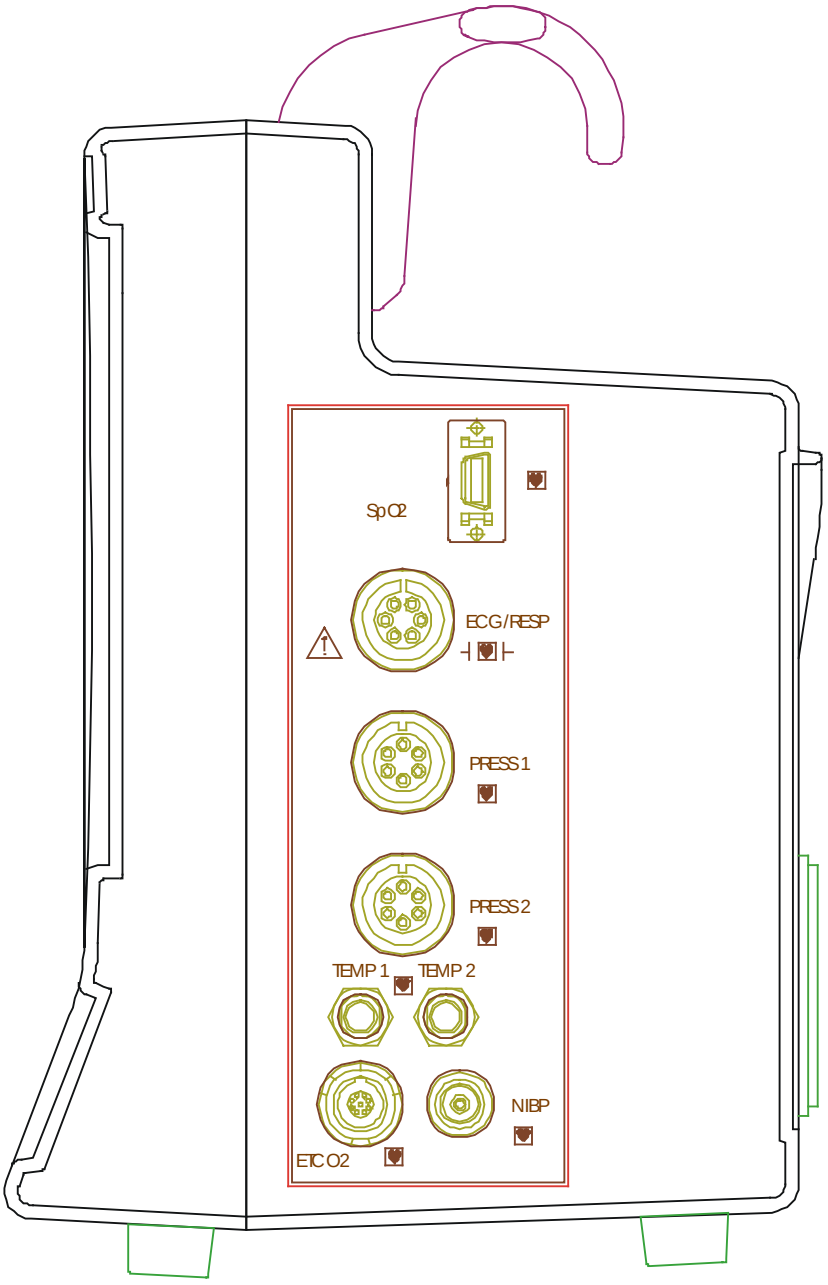
Stops the movement of the all waveforms on the display for closer evaluation. Press **FREEZE** again to resume movement.

Resets the audible and visual indicators for an alarm that has been activated.

Starts a printout at the optional recorder. The recorder normally plots waveforms. To define the waveform printout, use the menus accessed by pressing the **SYSTEM SETUP** key.

Displays Trend data. To define the trend display, see the trend display setup instructions.

Side Panel Connector



Display

Waveform Display

When the monitor is configured for all parameters, any of the following waveforms can be displayed:

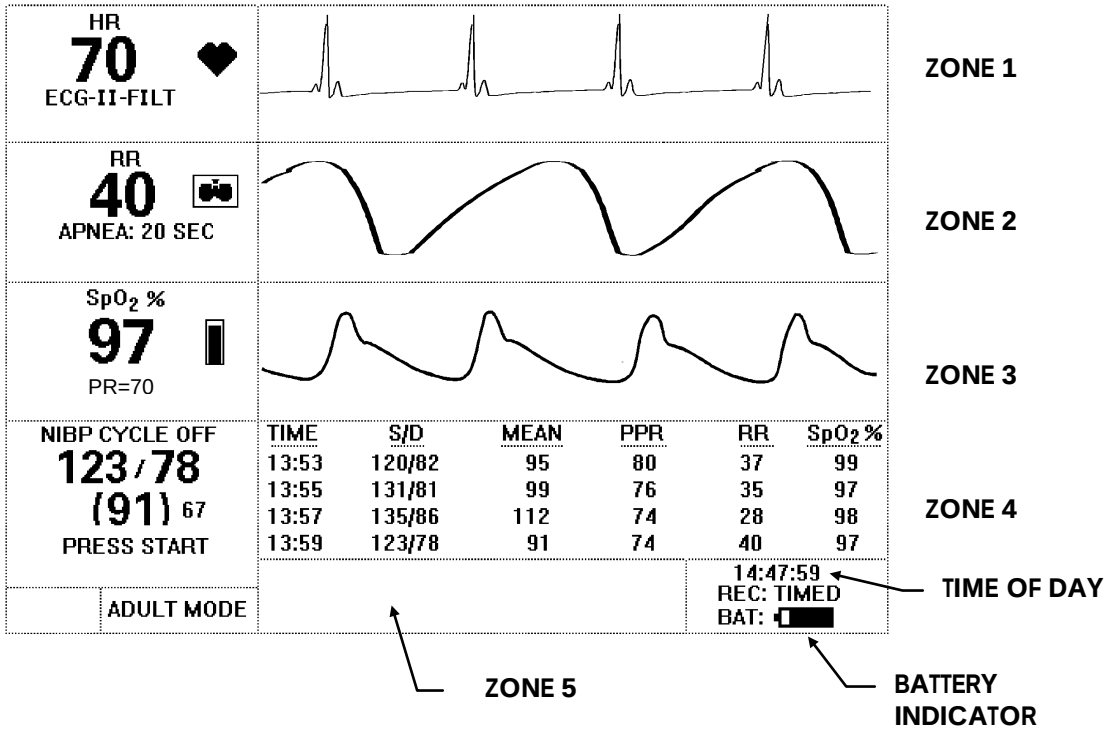
ECG
Respiration
Two Invasive Pressures (P1, P2)
Pleth (Pulse Oximetry)
EtCO2

Waveforms are updated with a moving bar at a rate of 6.25, 12.5, 25, or 50 mm/s, selected by the user. Waveform amplitudes are adjusted using the ECG Size selection in the menus and the **RESP SIZE** keys on the front panel. Invasive blood pressure scales are changed through the P1/P2 menu. A typical display is shown below.

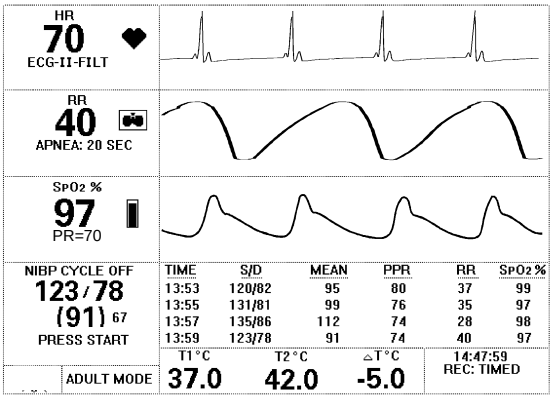
The display contains five zones, selectable through the menus.

ZONE 1: Can only display the ECG waveform or no waveform (OFF)
ZONE 2: Selectable to display waveforms of RESP, EtCO2, SpO_2, P1, P2, or OFF
ZONE 3: Selectable to display waveforms of RESP, EtCO2, SpO_2, P1, P2, or OFF
ZONE 4: Selectable to display waveforms of RESP, EtCO2, SpO_2, NIBP, P1, P2, Zones 3 & 4 P1 EXPAND, Zones 3 & 4 P2 EXPAND, Zones 3 & 4 P1/P2 EXPAND, or OFF
ZONE 5 (numeric only): Displays temperature readings with an area reserved to selectively display RESP, EtCO2, SpO_2, or OFF

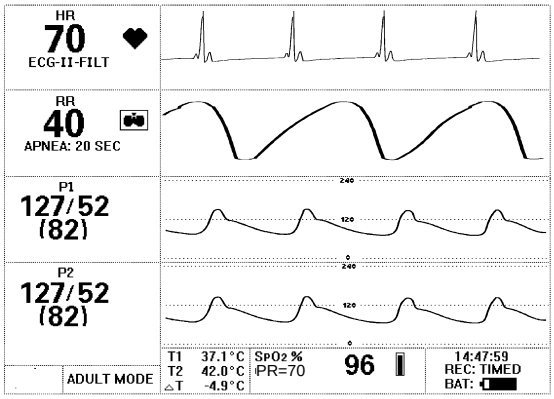
If invasive pressure is being monitored, Zones 3 and 4 combined can display one or both pressures on a single expanded scale that is twice the height of the normal pressure scale.



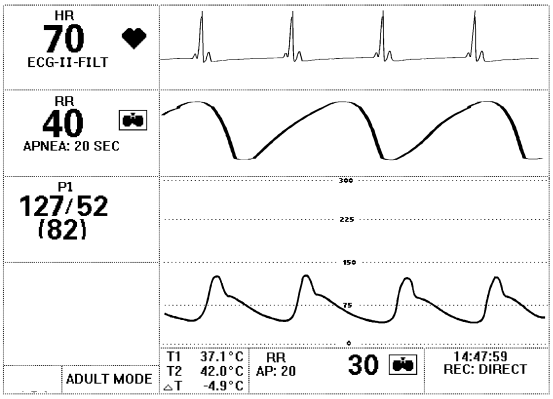
Temperature data displayed in Zone 5



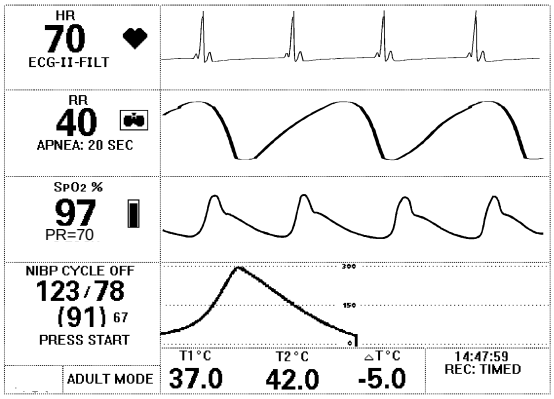
P1 displayed in Zone 3 and P2 displayed in Zone 4



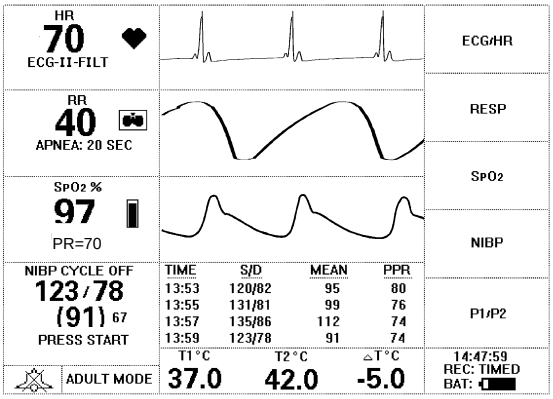
Expanded P1 displayed in Zones 3 and 4



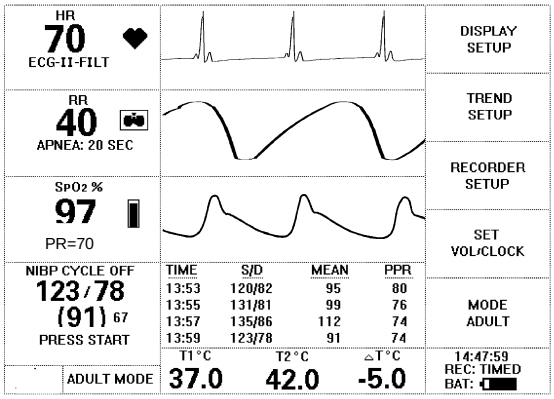
With NIBP Graph in Zone 4.



With **PATIENT SETUP** selections displayed



With **SYSTEM SETUP** selections displayed



NIBP Graph

To display the NIBP graph, press the PATIENT SETUP key, select [NIBP], and select [DATA FORMAT] until it is set at GRAPH.

The NIBP graph is shown in Zone 4 in one of the above illustrations. This oscillation profile assists the clinician in determining the validity of the NIBP measurement. An erratic or flat profile suggests that excessive motion or other artifact may have affected the measurement. A profile shaped like a bell curve represents a measurement not affected by motion or other artifact.

Alphanumeric Data

The following data appears on the display when the appropriate parameters are in use. Whenever possible, numeric data is displayed near related waveforms. When you select a display zone for a waveform, numeric data related to that waveform is also displayed in that zone. To display data without displaying the waveform, use Zone 5.

Time of Day- At the lower right-hand corner of the display.

Heart Rate- Upper left corner of the display with a symbol indicating the source of the heart rate.

Respiration rate and flashing respiration indicator- To the left of the waveform. if the waveform is displayed. Otherwise, at the bottom of display in Zone 5. Respiration rate can be computed from either impedance or EtCO2.

End Tidal CO_2 (EtCO2) - To the left of the waveform if the waveform is displayed. Otherwise, at the bottom of display in Zone 5.

Oxygen Saturation (SpO_2) and pulse oximeter bar graph- To the left of the waveform if the waveform is displayed. Otherwise at the bottom of the display in Zone 5.

Pressure Readings-one or two sets of readings- To the left of the waveform in the form: **syst/dias**
(mean)

Current NIBP Reading- At the lower left in the form: **syst/dias**
(mean)

Temperature- Three readings at the bottom of the display: Temp 1, Temp 2 and the difference between the two temperatures (Δ Temp).

The data display is blank for any parameter not in use.

Alarm Limits Display

A numeric display of current alarm limits settings. The alarm limits appear just below the numeric value of the corresponding parameter. This display appears when the **DISPLAY LIMITS** key is pressed.

Alarm Displays

When an alarm setting has been exceeded, a flashing alarm tag appears on the screen, indicating which alarm has been triggered. Each alarm tag appears in the same location where the limits for that alarm are displayed.

Trend Displays

NIBP Trend: A tabular display of the readings at the time of each NIBP measurement. The latest five readings are displayed, and the display can be scrolled to view previous readings.

CRG: Graphic Display of up to four minutes of beat-to-beat heart rate, SpO_2 and respiration effort. Whenever EtCO2 is being monitored, the EtCO2 waveform is used for the respiration portion of the CRG.

Trend: Graphic Display of up to 24 hours of averaged heart rate, SpO_2, respiration rate, and pressure readings.

Review Trend: Graphic and Numeric display of the most recent 24 hours of heart rate, SpO_2, respiration rate, and pressure readings at two different views: 6 Hour View displays 6 hours of data per window; and 30 Minute View displays 30 minutes of data per window. Data can be moved under the cursor to obtain parameters readings at specific point in time. Numeric value of heart rate, SpO_2, respiration rate, and invasive pressures is displayed over the cursor.

Alarms

The following is a list of alarms and ranges for which they can be set. When the alarm triggers, the alarm indicator flashes on the display and the audio alarm tone sounds. Pressing **ALARM RESET** turns off any alarms that have triggered. If the measurement returns to within the limits, the alarm turns off.

The **ALARM PAUSE** key disables the alarms for two minutes or until **ALARM PAUSE** is pressed again.

High heart rate: 15 to 300 bpm in 5 bpm increments

Low Heart Rate: 15 to 300 bpm in 5 bpm increments

High Resp Rate: 5 to 150 br/min in 5 br/min increments

Low Resp Rate: 5 to 150 br/min in 5 br/min increments

Temp High: 35ºC to 45ºC in 0.1ºC increments

Temp Low: 35ºC to 45ºC in 0.1ºC increments

NOTE: For additional Temp alarm conditions, see the Temperature Monitoring section of this manual.

EtCO2 High: 10 to 100 Torr in 2 Torr increments

EtCO2 Low: 10 to 100 Torr in 2 Torr increments

NIBP High: Selectable systolic, diastolic, or mean 10 to 300 mmHg in 2 mmHg increments

NIBP Low: Selectable systolic, diastolic, or mean 10 to 300 mmHg in 2 mmHg increments

NOTE: For additional NIBP alarm conditions, see the NIBP Monitoring section of this manual.

IBP High: Selectable systolic, diastolic, or mean; -40 to 300 mmHg in 2 mmHg increments

IBP Low: Selectable systolic, diastolic, or mean; -40 to 300 mmHg in 2 mmHg increments

NOTE: Invasive and non-invasive pressures can be set to alarm on systolic, diastolic, or mean.

High SpO_2: 50 to 100%in 1% increments

Low SpO_2: 50 to 100% in 1% increments

Asystole: R-to-R interval >6 seconds

No Pulse: When triggering from pleth or invasive pressure, the interval between heartbeats exceeds six seconds

Lead Off: Detached lead or offset potential ≥0.5 V. The ALARM RESET key does not reset this alarm

Check Leads: Electrode impedance is >4 kΩ

Coincidence: When QRS and respiration triggers are synchronized for eight consecutive events

Apnea: Absence of detectable respiration activity for 5, 10, 15, or 20 seconds, selectable.

Priority Alarms Feature (If present)

Note: Priority alarms may be enabled via the CONFIGURATION MENU (see operation and maintenance manual).This section applies only if priority alarms are PRESENT (default is ABSENT)

There are two types of Priority alarms schemes. Scheme 1 prioritized the alarms into 3 groups while Scheme 2 prioritized the alarms into 4 groups. The table below describes the color and audio associated with each alarm and scheme.

	SCHEME 1		SCHEME 2	
Priority	**Color**	**Audio Type**	**Color**	**Audio Type**
High	Red	Rapid Beeps	Red	Siren
Medium	Yellow	Slower Beeps	Yellow	Warble
SpO2 High	N/A	N/A	Light Blue	Alternate tones
Low	White	Longest Beeps	White	Tone

The alarms are grouped as follows:
High Priority:
- Asystole / No Pulse
- Apnea / No Resp
- Heart Rate (high/low)

Medium Priority:
- Respiration rate (high/low)
- SpO2% (high/low). If Scheme 2 is selected this alarm becomes a separate priority.
- NIBP pressures (high/low)
- Invasive pressures (high/low)
- EtCO2 (high/low)
- InCO2 (high)

Low Priority:
- Temperature (high/low)
- Miscellaneous alerts (i.e.: Coincidence)
- All non-physiological alerts (i.e.: Lead Off, Check Cuff, etc)

Note: The Priority Alarm feature incorporated into the Vital-Guard 450C is intended to provide the user with a graded visual and audible indication of both the Patient's and the Monitor's status. It is the responsibility of the users to ensure that they use good clinical judgement to determine how they should respond to any alarm.

Rear Panel

The following are located on the rear panel.

ANALOG OUTPUT: An analog output that can be used for connecting to an external device. Signals on this connector include ECG, respiration, invasive pressures, pleth, heart rate, SpO_2, alarm out, remote recorder, and optional nurse call.
Do not attempt to connect a cable to this connector without contacting your Biomedical Engineering Department or the Ivy Service Department. This is to insure the connection complies with leakage-current requirements of one of the following applicable standards: Underwriters Laboratories UL 2601-1, Canadian Standards Association CSA 601.1 No. M90 or Internal Electrotechnical Commission IEC 60601-1. The maximum non-destructive voltage that may be applied to this connector is 5 V dc.

ECG X1000: A ¼-inch phone socket that can be used for connecting to an external device using the ECG waveform and LEAD OFF indicator.

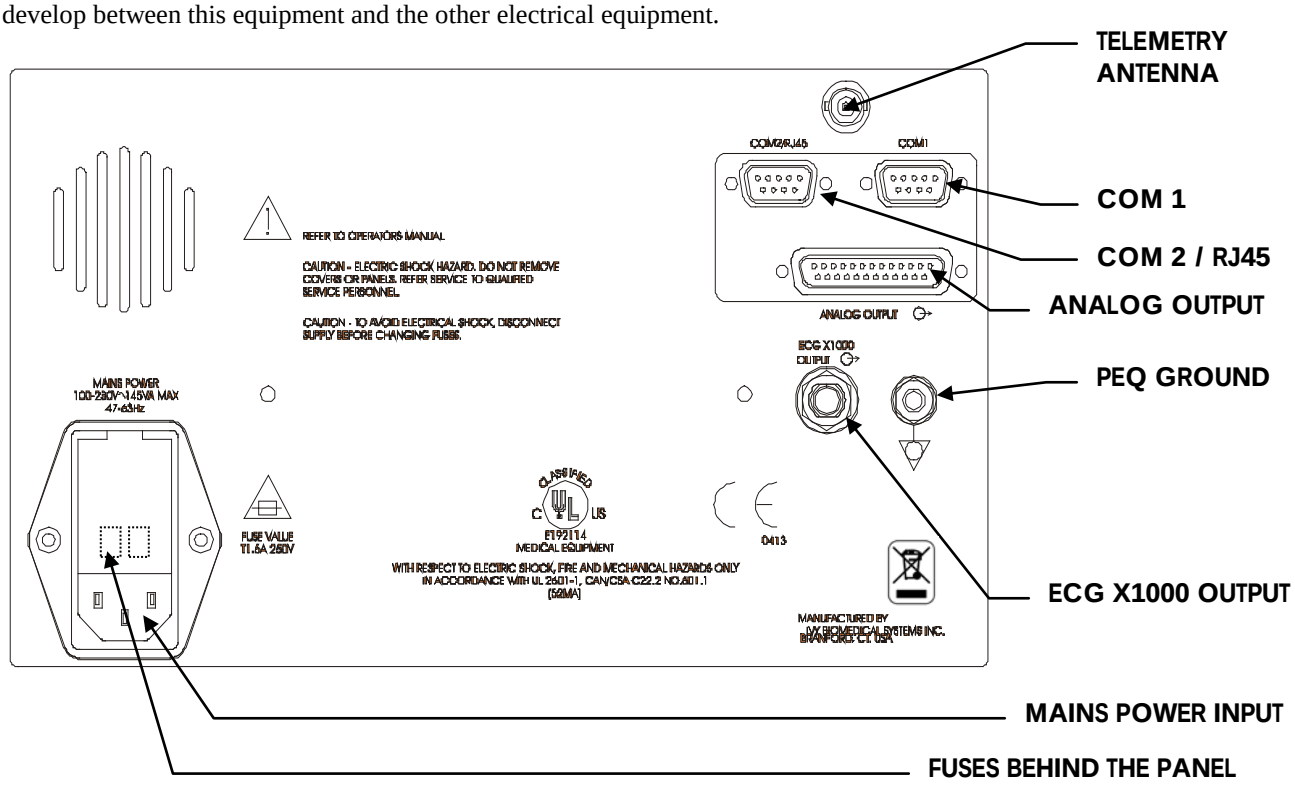
COM 1: A digital interface for network communication.

COM 2 / RJ45: A digital interface for network communication**.**

TELEMETRY ANTENNA: A BNC connector for the Telemetry System antenna.

CAUTION: When the Telemetry option is selected and installed in the Model 450C due to the technical limitations inherent with all wireless communications, IVY Biomedical Systems, Inc. cannot guaranty that all signals transmitted via the antenna will be received by the appropriate receiver or receiving device.

PEQ GROUND: Potential Equalization- Use this ground connection to ensure that no potential differences can develop between this equipment and the other electrical equipment.



Note: Parts and accessories used must meet the requirements of the applicable IEC 60601 series safety standards and essential performance standards, and/or the system configuration must meet the requirements of the IEC 60601-1-1 medical electrical systems standard.

ACCESSORIES (EQUIPMENT) – The use of ACCESSORY equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:

- use of the accessory in the PATIENT VICINITY; and
- evidence that the safety certification of the ACCESSORY has been performed in accordance to the appropriate IEC 60601-1 and/or IEC 60601-1-1 harmonized national standard.

Menu Structure

Settings for all options for the Model 450C are made through a series of menus that appear at the right side of the display. You access the menus by pressing the **PATIENT SETUP** or **SYSTEM SETUP** key. The **PATIENT SETUP** key is for settings involving the parameters, while the **SYSTEM SETUP** key is for general monitor settings.

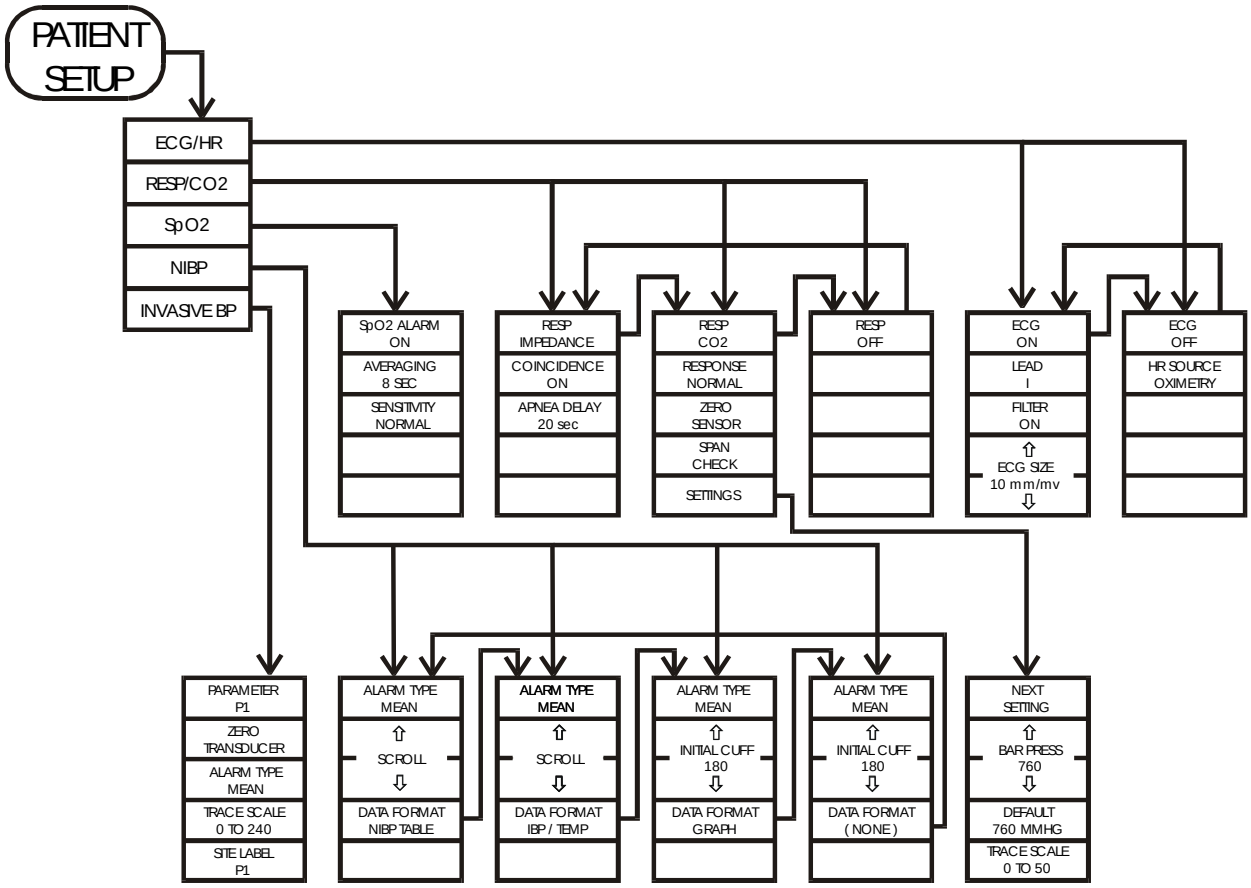
When menus are displayed, if no key is pressed for a period of 30 seconds, the monitor returns to normal display.

NOTE: If the monitor beeps when you press a key, it indicates an invalid selection for the current mode or function.

The PATIENT SETUP Key

Press **PATIENT SETUP** to display the main menu, which allows you to select ECG, RESP, SpO_2, P1/P2, or NIBP menus. See the menu structure diagram below.

When the main menu is displayed, press **EXIT** to return to normal display.



PATIENT SETUP KEY SELECTION

ECG/HR
- ECG: ON, OFF
- LEAD: I, II, III, aVR, aVL, aVF, V
- FILTER: ON, OFF
- ECG SIZE: 1 TO 100 mm/mV

RESP/CO2
- RESP: IMPEDANCE, CO2, OFF
- COINCIDENCE: ON, OFF
- APNEA DELAY: OFF, 5, 10, 15, 20 s
- NO RESP DELAY: OFF, 5, 10, 15, 20 s

SETTINGS
- NEXT SETTING: BAR PRESS, N20, 02, NORMAL RESPONSE
- TRACE SCALE:0 TO 50, 0 TO 100 mmHg

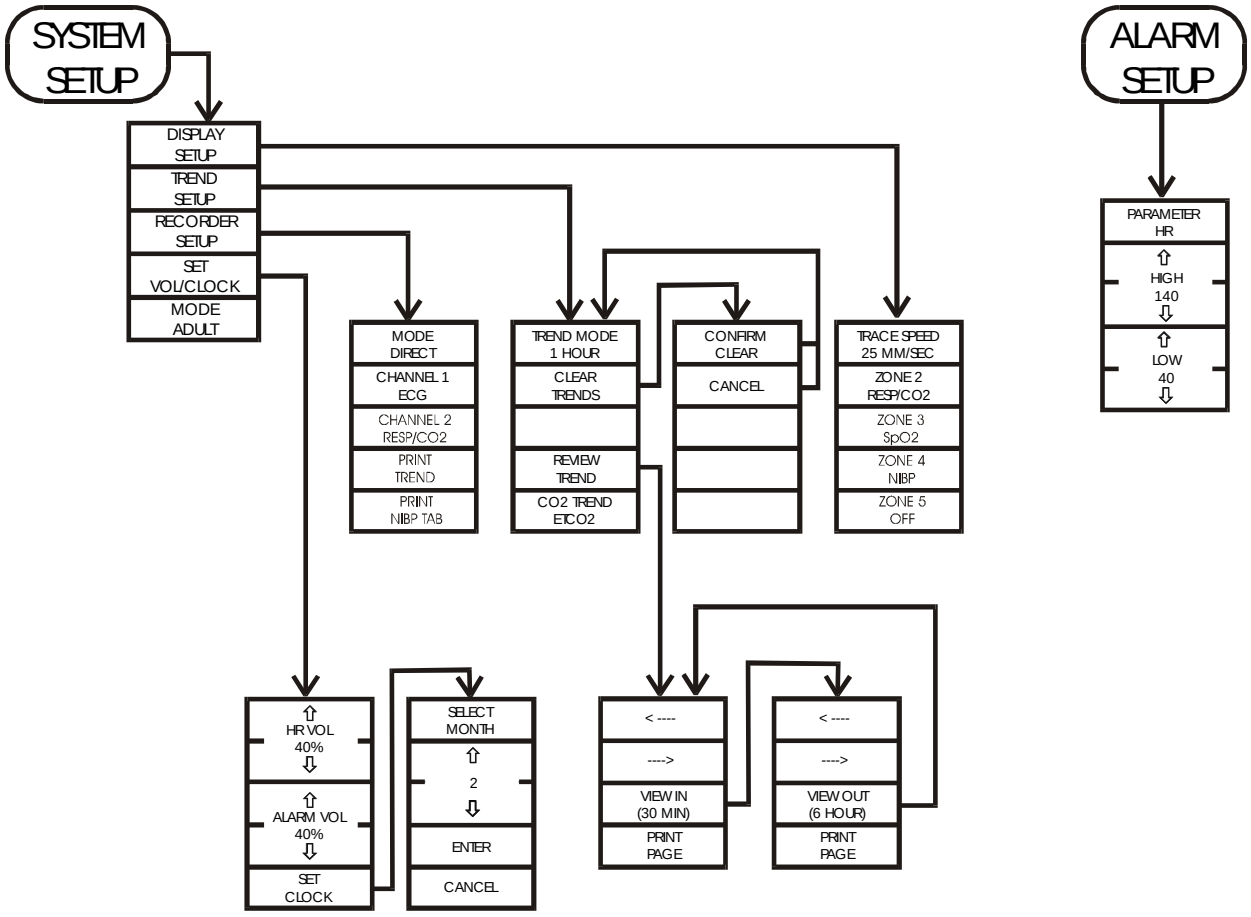
SpO2
- SpO2 ALARM: ON, OFF
- AVERAGING:6, 8, 10, 12,14, 16 SEC
- SENSITIVITY: NORMAL, HIGH

NIBP
- ALARM TYPE: MEAN, SYS, DIAS, OFF
- DATA FORMAT: NIBP TABLE, IBP/TEMP, GRAPH, NONE
- INITIAL CUFF: 50-250 mmHg (ADULT)
  50-150 mmHg (NEONATE)

INVASIVE BP 1&2
- PARAMETER: P1, P2
- ALARM TYPE: MEAN, SYS, DIAS, OFF
- TRACE SCALE: -30 TO 30, 0 TO 60, 0 TO 120, 0 TO 240, 0 TO 300 mmHg
- SITE LABEL: P1, ART1, CVP1, PA1, ICP1, UAC1, UVC1 P2, ART2, CVP2, PA2, ICP2, UAC2 & UVC2

The SYSTEM SETUP Key

Press **SYSTEM SETUP** to display the mode menu for setting audio volume, trace speed, display and recorder settings.
When the mode menu is displayed, press **EXIT** to return to normal display.



SYSTEM SETUP KEY SELECTION

DISPLAY SETUP
TRACE SPEED: 6.25, 12.5, 25, 50 mm/s
ZONE 2: OFF, RESP/CO2, SpO2, P1, P2
ZONE 3: OFF, RESP/CO2, SpO2, P1, P2
ZONE 4: OFF, RESP/CO2, SpO2, NIBP, P1, P2
EXPANDED 3&4: P1, P2, P1/P2
ZONE 5: OFF, RESP, SpO2, NIBP

TREND SETUP
TREND MODE: CRG, 1, 8, 12, 24 hrs.
CO2 TREND: ETCO2, RR

ALARM SETUP KEY SELECTIONS

PARAMETER: HR, RR, SpO2, NIBP, P1, P2, ETCO2, INCO2, T1 & T2 (if active)

RECORDER SETUP
MODE: DIRECT, TIMED, DELAY, AUTO, CRG, REMOTE
CHANNEL 1: ECG, RESP/CO2, PLETH, P1, P2
CHANNEL 1: ECG, RESP/CO2, PLETH, P1, P2, OFF

SET VOL/CLOCK
HR VOL: OFF, 20, 40, 60, 80, 100%
ALARM VOL: 20, 40, 60, 80, 100%
SET CLOCK
SELECT: MONTH, DAY, YEAR, HOUR, MINUTE

MONITOR SETUP

To setup the instrument for operation:

1. Plug the ac line cord into a power source providing the proper voltage.

2. Press the **ON/STANDBY** key at the bottom of the front panel to turn the unit on.

3. Connect the patient cable to the ECG/RESP connector on the right side panel.

4. If end tidal CO_2 is to be monitored, connect the Sensor cable to the $ETCO_2$connector on the right side panel.

5. If pulse oximetry is to be monitored, connect the sensor and the pulse oximetry cable to the SpO2 connector on the right side panel.

6. If NIBP is to be monitored, connect the NIBP hose to the NIBP connector on the right side panel.

7. If invasive pressure is to be monitored, connect the pressure transducer cable to the PRESS 1 or PRESS 2 right side panel connector.

8. If temperature is to be monitored, connect the temperature sensor cable to the TEMP 1 or TEMP 2 right side panel connector.

Adult/Neonate Modes

The Model 450C has mode settings for both adult/pediatric and neonatal monitoring. In general, the neonate mode is used for patients less than one year old. All other patients should be monitored using the adult mode.

When monitoring NIBP, set the monitor to neonate mode whenever a neonatal cuff is being used.

Select **Adult** or **Neonate** monitoring mode as follows:

1. Press the **SYSTEM SETUP** key to display the mode menu.

2. Use the [MODE] menu selection to select either ADULT or NEO. The current selection is displayed on the left side of the screen near the bottom.

3. Press **EXIT** to return to the normal display.

Heart Rate Source

Normally, heart rate is computed using the ECG waveform. If ECG is set to OFF, heart rate can be computed using the oximetry, P1, or P2 waveforms.

1. Press the **PATIENT SETUP** key.
2. Select [ECG/HR] and select [ECG], setting it to OFF. The [HR SOURCE] selection appears.
3. Use the [HR SOURCE] selection to select OXIMETRY, P1, P2, or NONE.

Trace Speed

1. Press the **SYSTEM SETUP** key to display the mode menu. Then select [DISPLAY SETUP].
2. Use the [TRACE SPEED] selection to select the trace speed. Selections are 6.25, 12.5, 25, and 50 mm/s.
3. Press **EXIT** to return to the normal display.

Set Time and Date

1. Press the **SYSTEM SETUP** key to display the mode menu. Then select [SET VOL/CLOCK] and select [SET CLOCK] from the next menu.
2. The first setting is for MONTH. Use the ⇧ and ⇩ keys to increase or decrease the month setting.
3. Press [SELECT] to move to the DAY setting. Use the ⇧ and ⇩ keys to increase or decrease the day setting.
4. Press [SELECT] to move to the YEAR setting. Use the ⇧ and ⇩ keys to increase or decrease the year setting.
5. Press [SELECT] to move to the HOUR setting. Use the ⇧ and ⇩ keys to increase or decrease the hour setting.
6. Press [SELECT] to move to the MINUTE setting. Use the ⇧ and ⇩ keys to increase or decrease the minute setting.
7. When all date and clock settings are correct, select [ENTER] to enter the settings into the monitor's memory.

Display Setup

1. Press the **SYSTEM SETUP** key to display the mode menu.

2. Select [DISPLAY SETUP] to display the Zone Select menu.

3. Use the key next to each zone to select the display for the corresponding zone. Zone 5 is numeric only.

   Selections are as follows.

Zone 1	Zone 2	Zone 3	Zone 4	Zone 5
ECG	Off	Off	Off	Off
	Resp/CO_2	Resp/CO_2	Resp/CO_2	Resp/CO_2
	SpO_2 (Pleth)	SpO_2 (Pleth)	SpO_2	SpO_2
	P1	P1	NIBP	NIBP
	P2	P2	P1	
			P2	
			P1 Expanded	
			P2 Expanded	
			P1/P2 Expanded	

   Each zone can also be set to off, except Zone 1, which is always ECG.

   Temperatures are displayed in a portion of Zone 5.

NOTE: The above selections are available when the indicated parameters are included in the monitor's configuration and are being used.

4. Press **EXIT** to return to the normal display.

5. To display expanded invasive pressure waveforms, use the Zone 4 setting.

Data and Waveforms Color Setup

1. Turn the monitor OFF.

2. Simultaneously press the **SYSTEM SETUP** key and the **ON/STANDBY** button.

3. Use the ⇧ and ⇩ keys to change the parameter.

4. Press [CHANGE COLOR] to change the color.

5. Press [DEFAULTS] to reset the colors.

6. Press **ON/STANDBY** button twice to return to normal display.

Audio Setup

1. Press the **SYSTEM SETUP** key to display the mode menu.
2. Select [SET VOL/CLOCK] to display the menu for setting HR and alarm volume.
3. Adjust the HR volume using [HR ⇧ and ⇩] keys.
4. Adjust the alarm volume using [ALARM ⇧ and ⇩] keys.
5. Press EXIT to return to the normal display.

Display Limits

To avoid clutter on the display, limits for parameter alarms are not displayed unless the Limits Display selection is set to ON.

To enable or disable Limits Display, press the **DISPLAY LIMITS** key during normal display.

Trend Displays

The 450C monitor has a trend display showing heart rate, SpO_2, P1, P2, and respiration rate. Time selections for this trend display are 1, 8, 12, and 24 hours. Another trend display is cardiorespirogram (CRG). The CRG displays the last four minutes of beat-to-beat heart rate, a compressed respiration signal, and SpO_2 trend, if the SpO_2 waveform is being displayed in the normal display.

Trend Setup

1. Press the **SYSTEM SETUP** key. The mode menu appears.
2. Select [TREND SETUP] to display the trend selection menu.
3. Use the [TREND MODE] selection to select the trend mode: 1, 8, 12, or 24 hours or CRG.
4. Press **EXIT** to return to the normal display.

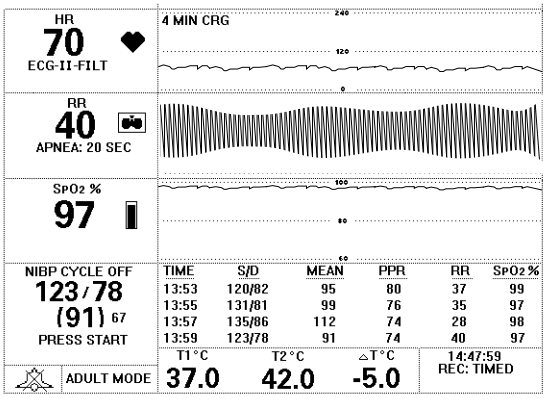
Trend Display

1. To display the trend selected in the trend setup, press the **TREND** key.

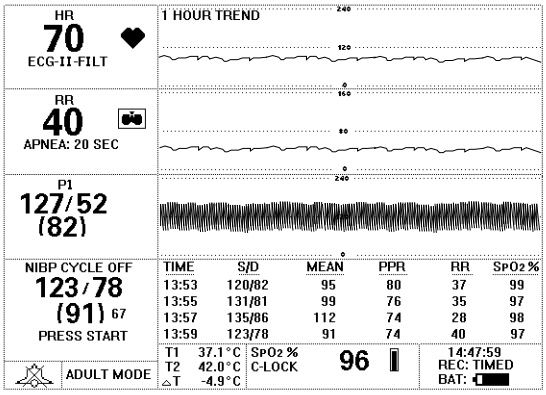
   The trends appear on the display for the parameters selected in display setup.
2. Press TREND again to return to the normal display.

NOTE: The monitor continuously accumulates trend data for all parameters in use. Any trend can be displayed by changing the setup in the menus.

CRG Display



1 Hour Trend Display



Review Trend Displays

Review trend collects the most recent 24 hours of heart rate, SpO_2, invasive pressures, and respiration rate. The monitor exhibits them at two different trend views:

1. The 6 Hour view trend displays 6 hours of data per screen (1 dot = 1 minute).

2. The 30 Minute view shows 30 minutes of data per screen (1 dot = 5 seconds).

In either case, a cursor indicates the numeric value of the parameters. The data can be moved under the cursor to review the accumulated information at any specific time within the last 24 hours.

NOTE: The 450C monitor is constantly gathering data of heart rate, SpO_2, invasive pressures, and respiration rate to be used in the Review Trend. However, if the monitor is turned off the data will be erased.

To access the Expanded Trend mode:

1. Press the **SYSTEM SETUP** key. The setup menu appears.

2. Select [TREND SETUP] to display the trend selection menu.

3. Select [REVIEW TREND] to enter the expanded trend display.

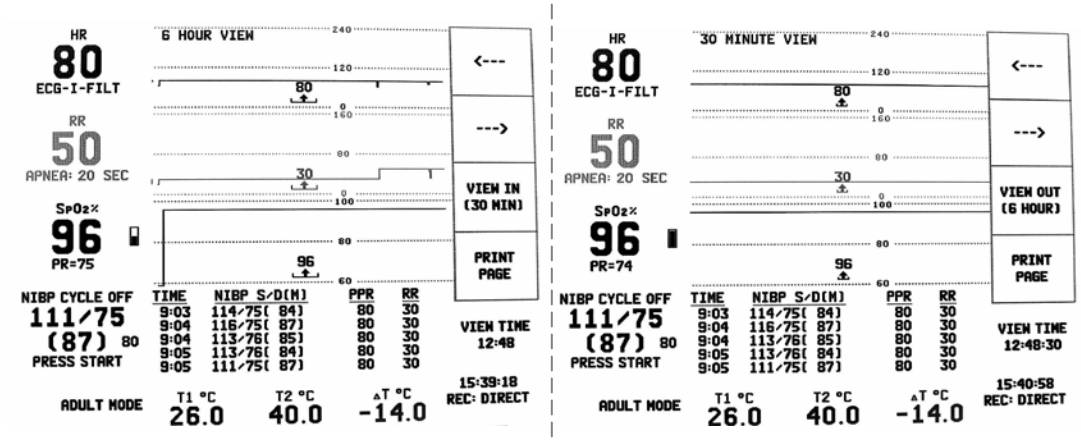
4. Press [←] or [→] to move the cursor a long the trend.

5. Select [VIEW IN/OUT] to toggle between 6 hour view and 30 minute view displays.

6. Press **EXIT** to return to the normal display.

NOTE: The 450C monitor should be ON for at least one minute before Review Trend can be accessed.

6 Hour View **30 Minute View**



Clear Trend Data

Use the following procedure to delete all trend data in memory (including NIBP tabular trend data) without turning power off.

1. Press the **SYSTEM SETUP** key. The mode menu appears.
2. Select [TREND SETUP] to display the trend selection menu.
3. Select [CLEAR TRENDS]. The selections [CONFIRM] and [CANCEL] appear.
4. Select [CANCEL] to abort the clear trends procedure. To clear the trend data, select [CONFIRM].

Default Settings

User settings are stored in non-volatile memory. The monitor powers up with the same settings that were in effect when power was last turned off.

To reset the monitor to the default settings press **TEST** key and **ALARM RESET** key simultaneously while applying power to the monitor by pushing the **ON/STAND BY** key.

Default Settings

System Setup
Trace Speed: 25 mm/sec
Displayed parameters:
Zone 1: ECG
Zone 2: RESP
Zone 3: SpO2
Zone 4: NIBP
Zone 5: Off
Trend Mode: One hour
Recorder: direct
HR Volume: 40%
Alarm Volume: 100%
Monitoring Mode: Adult

ECG
Lead: I
Filter: ON
ECG size 10mm/mv
HR limits (140-40)

RESPIRATION
Resp: Impedance
Apnea delay: 20 sec
Coincidence: ON
RR limits (60-10)

SpO_2
SpO2 Alarm: ON
Averaging: 8 sec
Sensitivity: Normal
Alarm limits (100-90)

NIBP
Cycle: OFF
Data Format: NIBP table
Alarm Type: Mean
Alarm limits (160-80)

TEMP (Both channels)
Alarm limits: Off

IBP 1
Alarm Type: Mean
Alarm limits (120-60)
Trace Scale: 0 to 240 mmHg
Site Label: P1

IBP 2
Alarm Type: Mean
Alarm limits (120-60)
Trace Scale: 0 to 240 mmHg
Site Label: P2

$EtCO_2$
No Resp Delay: 20 sec
Bar. Press: 760mmHg
Trace Scale: 0 to 50
Alarm limits (50-300)

BATTERY OPERATION

Internal Battery

The model 450C is equipped with two internal batteries. This allows the monitor to operate for 2½ hours under its own power.

In the event of a mains power failure, the model 450C will automatically switch to battery operation.
A BAT indicator in the lower right corner of the display graphically displays the approximate remaining charge of the battery: full, 75 %, 50 %, 25 %.

When the remaining battery charge is less than 20 minutes, the BAT indicator flashes the word LOW and an audio tone sounds every 15 seconds.

The battery is continuously charged whenever the ac power is connected, even when the monitor is turned off. Charging time when the battery is fully discharged is 12 hours.

If monitor is not in regular service, i.e. weekly use, to ensure maximum battery life, it is recommended that, at least once a month, the unit be run on battery until it turns itself off and then recharged.

Remove the batteries if the monitor will not be in regular use for more than six months.

Status of the Battery

The model 450 has three LED's (label as Charged, Charging and Battery Fault) to indicate the status of the battery. They are located in the bottom left corner of the faceplate. The following table shows the status of the battery depending on the action (ON, OFF or FLASHING) of the LED's.

Status of the Battery	Charged LED	Charging LED	Battery Fault LED
Battery Absent	OFF	OFF	ON
Pre-charge qualification	OFF	FLASHING	OFF
Fast charging	OFF	ON	OFF
Maintenance charging	ON	OFF	OFF
*Charge Pending (Temperature out of range)	X	X	FLASHING
**Fault	X	X	ON

*If the temperature of the battery exceeds 116 ^{o}F (47 ^{o}C) the battery will not charge and will remain in a Charge Pending status.
**If Fault condition occurs replace the batteries immediately.

Removing the Battery

Refer to Disassembly and Assembly section of the Operation and Maintenance Manual to find out how to remove the batteries.

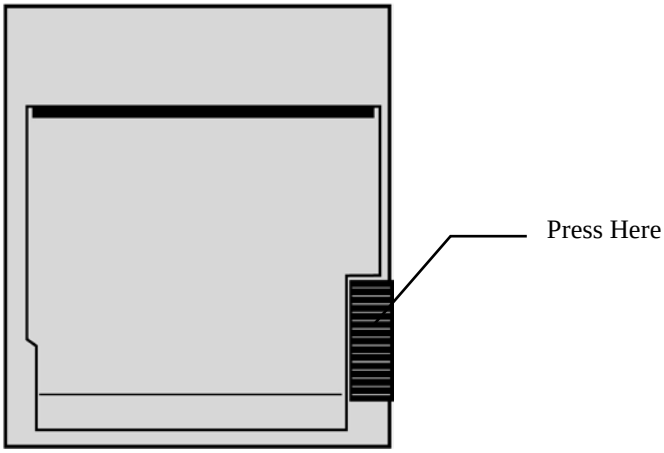
WARNING: To avoid risk of fire, replace only with the same type battery (Ivy Part No. 110007).

RECORDER OPERATION

Changing Paper

Replace the roll of thermal paper as follows.

1. Press the paper eject button to open the door at the front of the recorder.



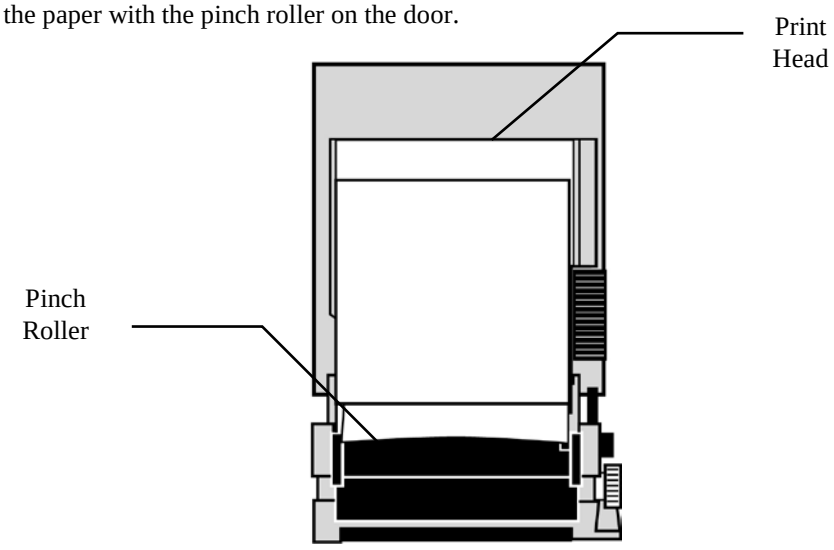
   If the door does not open completely, pull it toward you until it is completely open.

2. Reach in and remove the spent paper core by pulling it gently toward you.

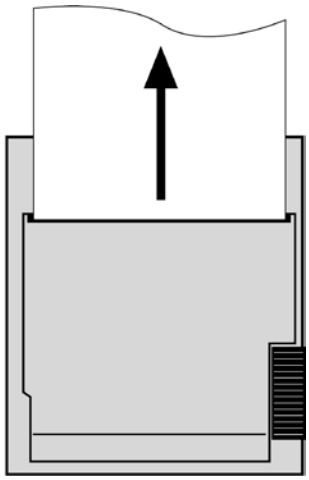
3. Place a new paper roll between the two round tabs of the paper holder.

4. Pull some paper from the roll. Make sure the sensitive (shiny) side of the paper faces the print head. The shiny side of the paper normally faces inside the roll.

5. Align the paper with the pinch roller on the door.



6. Hold the paper against the pinch roller and close the door.



Recorder Menus

The recorder user interface is through the menu structure of the 450C.

1. Press the **SYSTEM SETUP** key to display the system menu.

2. Select [RECORDER SETUP] to display the recorder menu.

NOTE: At the start of each printout, the printer produces a header consisting of the current readings for all parameters in use at the time of the printout, whether the parameter is displayed or not.

Recorder Modes

From the recorder menu, use (MODE) to select the printing mode to be used. Selections are DIRECT, TIMED, DELAY, AUTO, CRG, and REMOTE.

The print mode is indicated in the lower right corner of the display.

Direct

To print in direct, press the **PRINT** key. Press **PRINT** again to stop printing.

The plot is preceded by a header which contains all parameter readings and the time/date.

The speed of the plot and vertical resolution are the same as the display. The plot is labeled with the speed of the plot in mm/s, the recorder mode, and the parameters.

The following setup allows you to select which parameter is plotted in which channel of the recorder. If only one waveform is plotted or if the same waveform is selected for both channels, the recorder is scaled to use the entire 40 mm. If two different waveforms are selected, the recorder splits the plot into two 20 mm channels.

Use the following procedure to select the waveforms for each channel.

1. From the recorder menu, press the [CHANNEL 1] menu key to select the waveform to be printed on Channel 1.

2. Press the [CHANNEL 2] menu key to select the waveform to be printed on Channel 2.

   Selections for each channel are ECG, Respiration, $ETCO_2$, SpO_2 (Pleth), P1, and P2. Channel 2 can also be set to OFF. Whenever $ETCO_2$ is being monitored, the $ETCO_2$ waveform is used for respiration.

Timed

TIMED mode starts by pressing **PRINT** and prints for 30 seconds.

The speed of the plot and vertical resolution are the same as the display. The plot is labeled with the speed of the plot in mm/s, the recorder mode, and the parameters.

Delay

Delay mode plots the 15 seconds before and 15 seconds after the occurrence of an alarm condition. The parameters printed are those selected as described in the Direct Mode section.

The speed of the plot and vertical resolution are the same as the display. The plot is labeled with the speed of the plot in mm/s, the recorder mode, and the parameters.

With no alarm, pressing **PRINT** starts a printout that includes the 15 seconds before and the 15 seconds after pressing the key. An asterisk marks the time when the key was pressed or the alarm occurred.

The plot is preceded by a header which contains all parameter readings and the time/date.

Whenever delay mode is enabled, REC DELAY is displayed in the lower right corner of the display.

Auto

Parameters to be printed are selected based on the alarm. The printout is the same as in delay mode except that when an alarm triggers the recorder, the parameters are selected automatically. If the recording is started by pressing the **PRINT** key, the selected parameters are printed.

The following are the parameters printed for each type of alarm.

Type of Alarm	**Traces Printed**
ASYSTOLE	Single-trace ECG
HR	Single-trace ECG, SpO_2 (Pleth), P1, or P2 (based on HR source)
NO PULSE	Single-trace SpO_2 (Pleth), P1, or P2 (based on HR source)
APNEA	ECG, Respiration
COINCIDENCE	ECG, Respiration
RR	ECG, Respiration
SpO_2	ECG, SpO_2 (Pleth)
NIBP	Single-trace ECG
IBP1	ECG, P1
IBP2	ECG, P2

CRG

The recorder plots the CRG as two trend waveforms. The heart rate trend occupies the top half, and the compressed respiration occupies the lower half. If CRG is selected and respiration is not being monitored, HR only is printed. The trend is plotted at 1 mm/s. The plot is preceded by a header containing all the parameter readings and time/date.

From the recorder menu, use [MODE] to select the CRG mode. While the recorder is in CRG mode, REC CRG is displayed in the lower right portion of the display.

When menus are not displayed, press **PRINT**. The recorder then prints the real time CRG at 1 mm/s until you press **PRINT** again.

Remote

REMOTE mode will activate the recorder at a central station.

Print Trend

To print trends, select [PRINT TREND] from the [RECORDER SETUP] menu.

The recorder prints the trends as they appear on the display. The trend is scaled to appear as it does on the display.

The strip starts with a header, which contains the time and date and prints current readings for all measured parameters. Each trend is then plotted sequentially. The parameter, vertical scaling, and total time of the trend is printed with each trend. The vertical axis is printed at the start of the plot, and the horizontal time divisions are indicated. The resolution of the trend printout is:

1 hour	5 min/cm
8 hours	30 min/cm
12 hours	45 min/cm
24 hours	90 min/cm

The contents of the trend buffers at the settings currently selected in the trend menu are printed. The system prints the selected trends sequentially. Once the contents of the print trend buffer have been printed, the recorder exits this mode.

Print Review Trend

To print Review trends:

1. Press the **SYSTEM SETUP** key and then select [TREND SETUP] from the setup menu.

2. Select [REVIEW TREND] to enter the Review trend mode.

3. Press [PRINT PAGE], the recorder will start printing.

The resolution of the Review trend printout is:

6 Hour view View (6 hours):	0.5 hr / cm
30 Minute view (30 minutes):	2.5 min / cm

The recorder prints the trends as they appear on the display. The trend is scaled to appear as it does on the display. The strip starts with a header, which contains the time and date and prints current readings for all measured parameters. Each trend is then plotted sequentially. The parameter, vertical scaling, and total time of the trend is printed with each trend. The vertical axis is printed at the start of the plot, and the horizontal time divisions are indicated.

Print NIBP Tab

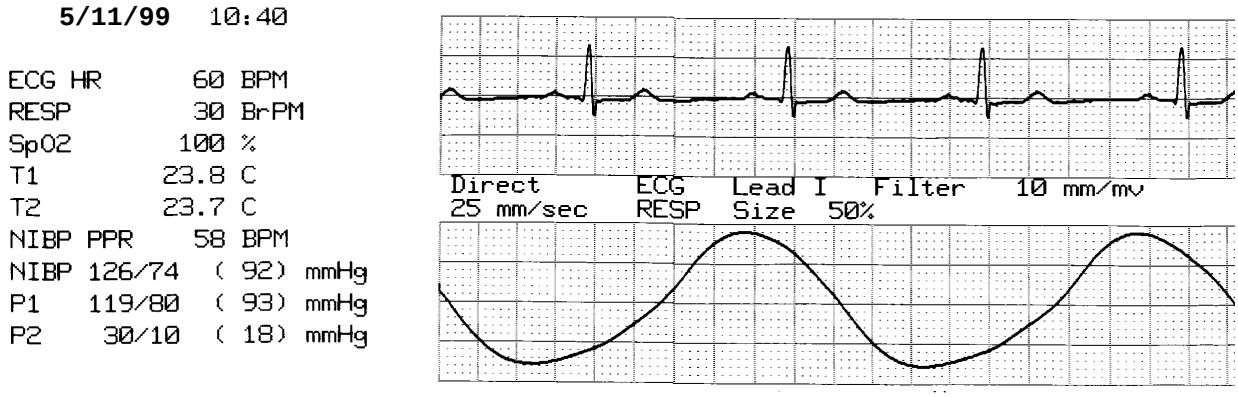
From [RECORDER SETUP] select [PRINT NIBP TAB] to print the entire contents of the tab buffer in columns as shown on the display.

Recorder Messages

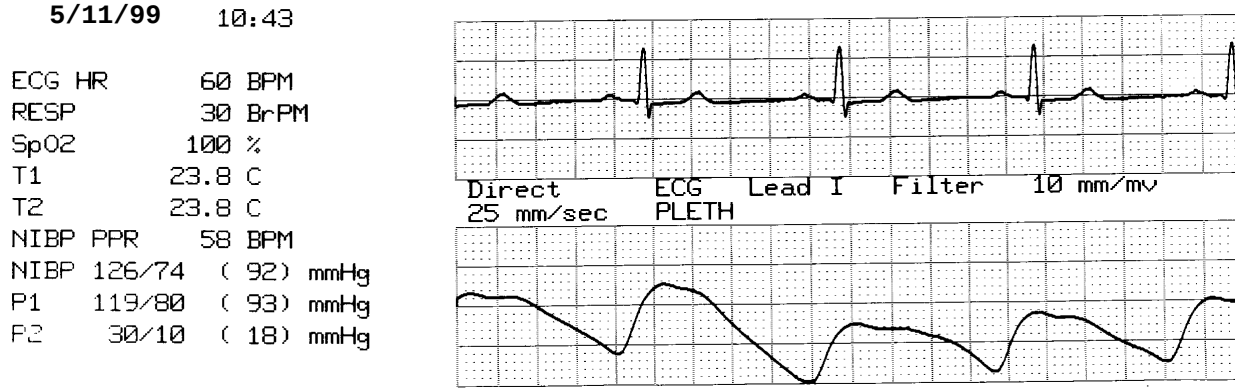
The following are messages that appear on the display to indicate the status of the recorder.

REC DIRECT**:** The recorder is ready to print in direct mode.
REC DELAY: The recorder is set for delay mode.
REC TIMED: The recorder is set for timed mode.
REC REMOTE: The recorder is set for remote mode.
DOOR OPEN: The recorder indicates that the door is open.
PAPER OUT: The recorder is out of paper.
REC ERROR: The monitor has detected a recorder failure.
REC INOP: Low battery voltage. Insufficient battery charge to operate the recorder.
REC HR: CRG is selected when respiration is not being monitored. HR only is printed.

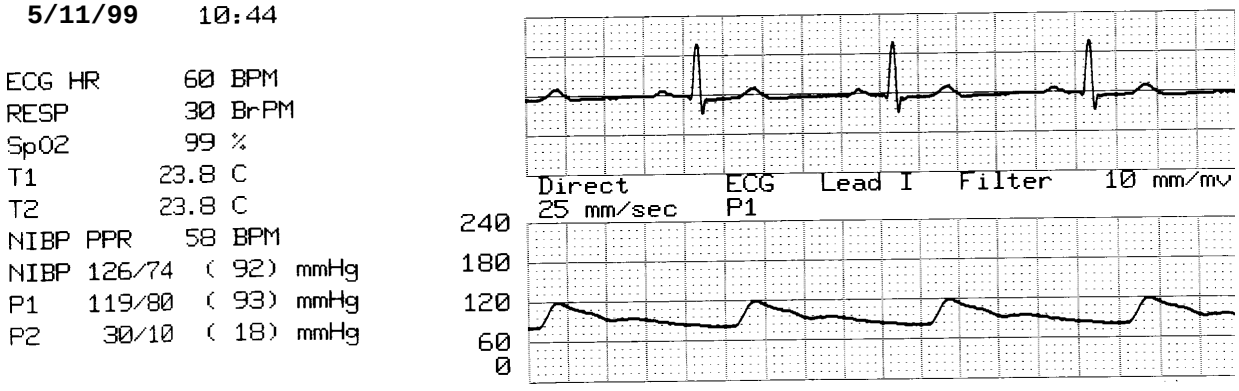
Example Printouts



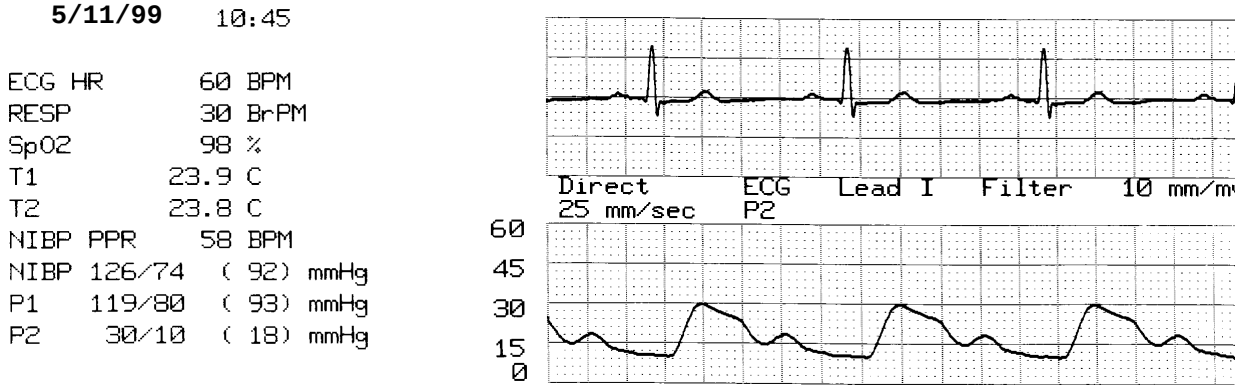
Direct Mode: ECG on Channel 1 and Respiration on Channel 2



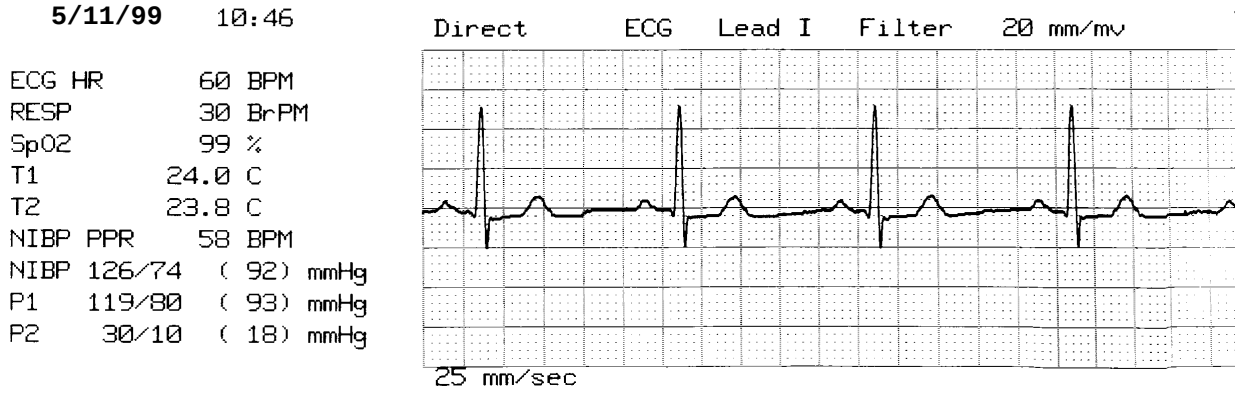
Direct Mode: ECG on Channel 1 and SpO_2 (Pleth) on Channel 2



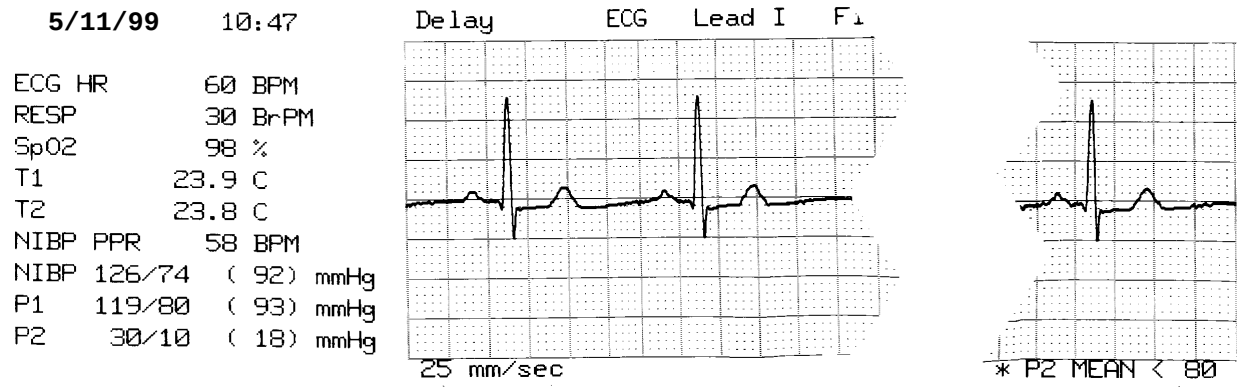
Direct Mode: ECG on Channel 1 and P1 on Channel 2



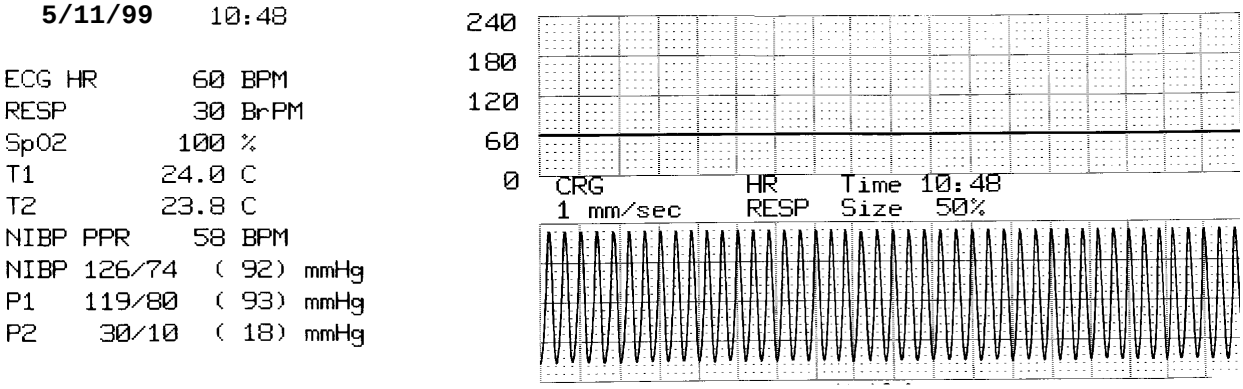
Direct Mode: ECG on Channel 1 and P2 on Channel 2



Direct Mode: ECG on Channel 1 and Channel 2 off



Delayed Mode: ECG on Channel 1 and Channel 2 off



CRG Mode

TIME	NIBP S/D (M)	PPR	RR	ET	SPO2%	P1 S/D (M)	P2 S/D (M)	T1	T2
21:50	271/269(270)	170	170	75	86	122/120(121)	122/120(121)	36.0	37.0
21:51	272/270(271)	171	171	75	86	123/121(122)	123/121(122)	36.1	37.1
21:52	273/271(272)	172	172	76	87	124/122(123)	124/122(123)	36.2	37.2
21:53	274/272(273)	173	173	76	87	125/123(124)	125/123(124)	36.3	37.3
21:54	275/273(274)	174	174	77	88	126/124(125)	126/124(125)	36.4	37.4
21:55	276/274(275)	175	175	77	88	127/125(126)	127/125(126)	36.5	37.5
21:56	277/275(276)	176	176	78	89	128/126(127)	128/126(127)	36.6	37.6
21:57	278/276(277)	177	177	78	89	129/127(128)	129/127(128)	36.7	37.7
21:58	279/277(278)	178	178	79	90	130/128(129)	130/128(129)	36.8	37.8
21:59	280/278(279)	179	179	79	90	131/129(130)	131/129(130)	36.9	37.9

NIBP Table

IBP/TEMP Table

ECG MONITORING

When ECG monitoring, the display shows the ECG waveform, the heart rate, heart rate limits (if **DISPLAY LIMITS** is selected), lead selection, adult/neonate mode, and alarm indications. Also, a heart symbol, pulse, or BP symbol flashes each time a heartbeat is detected, depending on whether the rate is being triggered by the ECG, pleth, or blood pressure waveform.

Safety Considerations

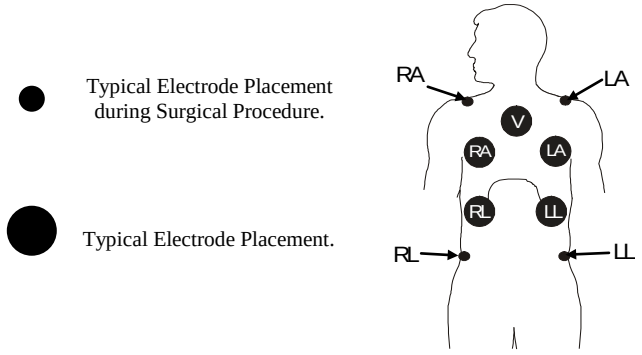
Disposable products are intended for single-use only. Do not attempt to re-use these products.

ECG Patient connections are electrically isolated **Type CF** . For ECG connections use insulated probes. Don't let patient connections contact other conductive parts, including earth. See instructions for patient connections in this manual.

This monitor is supplied with protected lead wires. *Do not use* cables and leads with unprotected lead wires having exposed conductors at the cable end. Unprotected lead wires and cables may pose an unreasonable risk of adverse health consequences or death.

Leakage current is limited internally by this monitor to less than 10 µA. However, always consider cumulative leakage current that can be caused by other equipment used on the patient at the same time as this monitor.

To avoid the potential of electrosurgery burns at ECG monitoring sites, ensure proper connection of the electrosurgery return circuit as described by manufacturer's instructions. If improperly connected, some electrosurgery units might allow energy to return through the electrodes.



Rate meters might continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely on rate meter alarms. Keep pacemaker patients under close surveillance.

For monitors used in Australia. For continued defibrillation protection and proper respiration monitoring use only patient cables with 1kΩ series resistors. Respiration circuit is tuned to operate with series resistors.

Patient Connections

To ensure compliance with safety and performance specifications, always use the patient cables and leads supplied by Ivy. Other cables might not produce reliable results.

NOTE: We recommend that you always use five-lead cables with monitors having the five-lead option. The use of many three-lead cables can cause poor quality signals and can inhibit the LEAD OFF alarm. When monitoring three leads, use the five-lead cable and remove the two unnecessary patient leads.

Use only high quality silver/silver-chloride electrodes or equivalent.

Use the following procedure for ECG monitoring:

1. Prepare each electrode site and apply the electrodes.

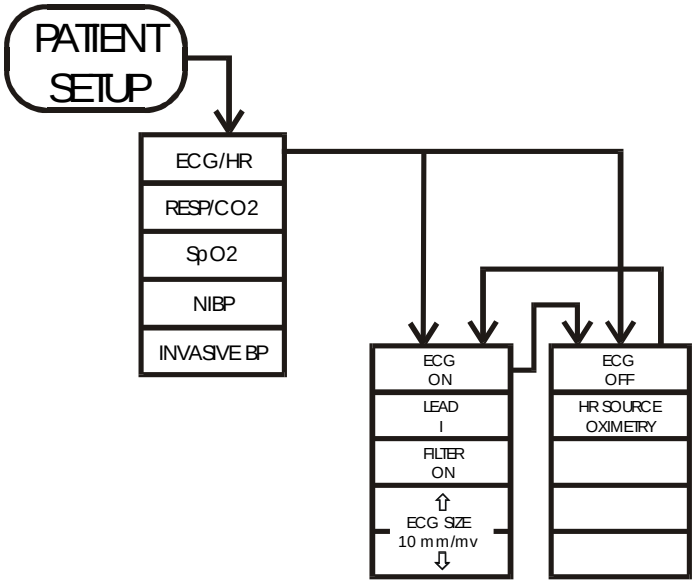
2. Connect the patient cable to the monitor's right side panel **ECG** input.

3. Attach the leads to the electrodes.

   Model 450C monitors with five-lead option can accommodate both three- and five-lead configurations.

4. Use the procedures described in the following sections for alarm limit settings, lead selection, amplitude adjustment, and enabling or disabling the filter. See the menu diagram below.

NOTE: For monitors designed to use both three- and five-lead cables, the LEAD OFF alarm tests only those leads that are relevant to the selected lead setting.



ECG Waveform Amplitude

Use the following procedure to adjust the amplitude (size) of the displayed ECG waveform.

1. Press the **PATIENT SETUP** key to display the main menu. Select [ECG/HR] to display the ECG menu.
2. Use the [ECG SIZE ⇧ and ⇩] selections to adjust the ECG size.
3. Press **EXIT** to return to the normal display.

HR Alarm Limits

1. Press the **ALARM SETUP** key to display the alarm limits menu.
2. If necessary select [PARAMETER] to display HR limits.
3. Use the [HIGH ⇧ and ⇩] selections to set the high heart rate limit.
4. Use the [LOW ⇧ and ⇩] selections to set the low heart rate limit.

   Each time you press a key, the corresponding limit changes by 5 bpm. The current settings are shown on the display when the front panel DISPLAY LIMITS selection is on.
5. Press **EXIT** to return to the normal display.

Lead Selection

1. Press the **PATIENT SETUP** key to display the main menu. Select [ECG/HR] to display the ECG menu.
2. Use the [LEAD] selection to set the lead selection.

   Available lead selections for five-lead ECG are I, II, III, aVR, aVL, aVF, and V. Selections for three-lead ECG are I, II, and III. If you select any other setting with only three leads connected, the monitor activates the LEAD OFF alarm.
3. Press **EXIT** to return to the normal display.

ECG Filter (Adult Mode Only)

1. Press the **PATIENT SETUP** key to display the main menu. Select [ECG/HR] to display the ECG menu.
2. Use the [FILTER] selection to set the filter to on or off. The filter on indication is FILT; the filter off indication is DIAG (diagnostic). The filter sets the frequency response of the displayed waveform as follows:

Filtered:	0.5 to 35 Hz
Unfiltered (diagnostic):	0.05 to 100 Hz

   In neonate mode, the filter is always on.
3. Press **EXIT** to return to the normal display.

ECG On/Off

The ECG can be turned off to monitor other parameters and not generate a LEAD OFF alarm. LEAD OFF is still functional for respiration.

1. Press the **PATIENT SETUP** key to display the main menu. Select [ECG/HR] to set the ECG to ON or OFF.

2. Press **EXIT** to return to the normal display.

Pacemaker

When a pacemaker has been detected, a **P** will start flashing in the heart symbol.

Rate meters might continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely on rate meter alarms. *Keep pacemaker patients under close surveillance.*

RESPIRATION MONITORING

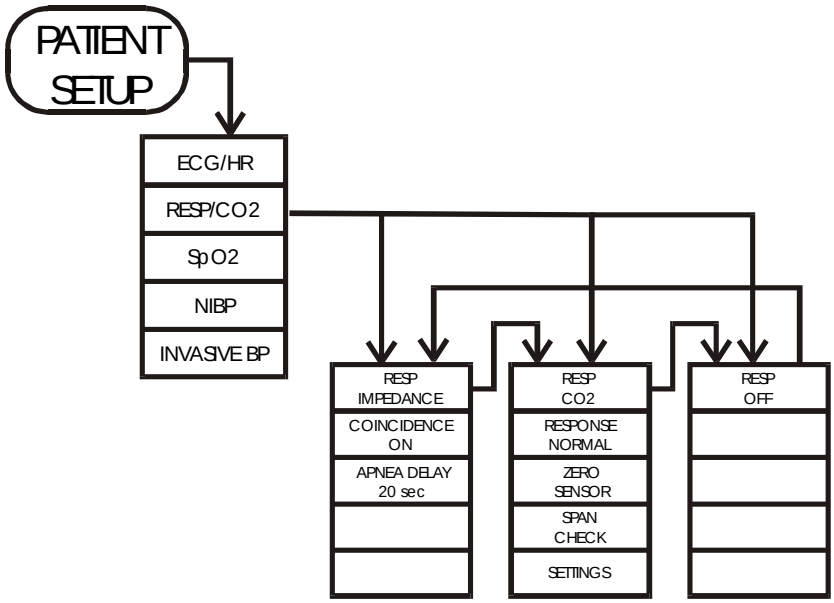
The monitor obtains the respiration signal through the same electrodes used for ECG. The lead selection does not affect the respiration signal.

WARNING: This monitor is supplied with protected lead wires. *Do not use* cables and leads with unprotected lead wires having exposed conductors at the cable end. Unprotected lead wires and cables may pose an unreasonable risk of adverse health consequences or death.

CAUTION: Do not use patient cables with internal resistors for defibrillation protection when monitoring respiration. Use of such cables might cause erratic respiration readings.

For proper respiration monitoring, cable capacitance between the RA and LA leads must be 400 ±100 pF.

The following diagram shows the respiration menus.



Respiration Size

The front panel up and down arrows control the relative size of the respiration signal.

Adjust the size so that it is not so large that the peaks of the waveform are clipped on the display but large enough so that the signal triggers the rate counter.

NOTE: The respiration detector requires the proper size setting to correctly detect respiration activity.

Apnea Delay

1. Press the **PATIENT SETUP** key to display the main menu. Select [RESP/CO_2] to display the respiration menu.

2. Use [APNEA DELAY] to set the delay at 5, 10, 15, 20 seconds, or off. Once this alarm is triggered, it remains on until a respiration is detected or **ALARM RESET** is pressed.

3. Press **EXIT** to return to the normal display.

Coincidence On/Off

In some cases, the true respiration rate and heart rate are the same. If this condition occurs for some time, the coincidence alarm can become a nuisance. To avoid this problem, the audio and visual coincidence alarms can be turned off.

Use the following procedure to enable or disable the coincidence alarm.

1. Press the **PATIENT SETUP** key to display the main menu. Select [RESP/CO_2] to display the respiration menu.

2. Use the [COINCIDENCE] selection to turn the coincidence alarm on or off.

3. Press **EXIT** to return to the normal display.

Respiration Rate Alarm Limits

1. Press the **ALARM SETUP** key to display the alarm limits menu.

2. Use the [PARAMETER] selection to display respiration rate (RR) limit settings.

3. Use the [HIGH ⇧ and ⇩] selections to set the high respiration rate limit.

4. Use the [LOW ⇧ and ⇩] selections to set the low respiration rate limit.

   Each time you press a key, the corresponding limit changes by 5 br/min. The current settings are shown on the display when the front panel DISPLAY LIMITS selection is on.

5. Press **EXIT** to return to the normal display.

Respiration On/Off

1. Press the **PATIENT SETUP** key to display the main menu. Select [RESP/CO_2] to display the respiration menu.

2. Use the [RESP] selection to turn respiration monitoring on or off.

3. Press **EXIT** to return to the normal display.

END TIDAL CO_2 MONITORING

General Description

The Ivy Model 450C monitor uses NonDispersive InfraRed (NDIR) gas measurement to determine CO_2 gas concentration. The NDIR measurement method uses fixed (non-scanning) frequencies of infrared (IR) light. NDIR measurement is based on the phenomenon that higher gas concentrations in a given volume of gas in the path of an IR light signal create more absorption of the IR light. Therefore, higher concentrations of an IR absorbing gas create a measurably lower transmission of the IR light.

Components

The following components make up an NDIR instrument. See the illustration below.

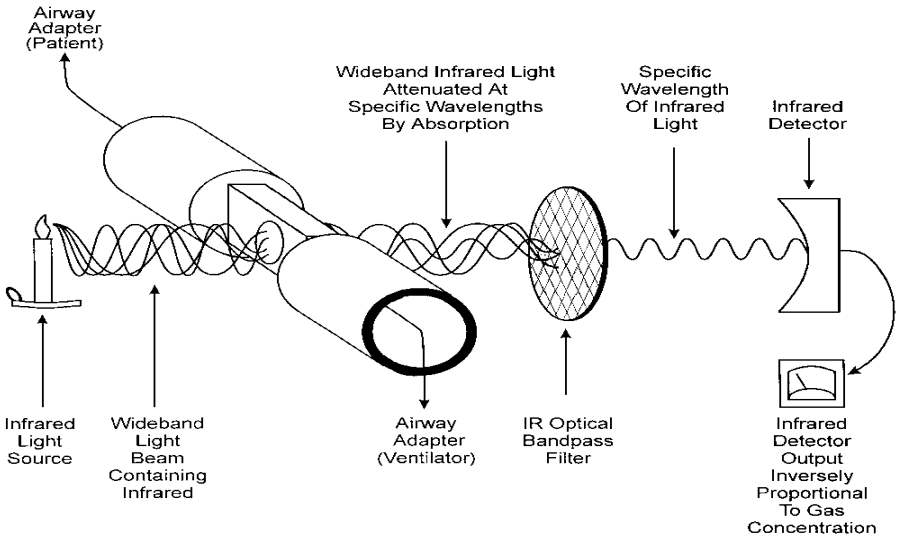
IR Source: A source of infrared light.

The infrared light source actually produces a wide range of light at frequencies covering the IR band and extending in either direction into the visible and ultraviolet spectra.

Sample Cell: The gas to be measured is transported into a sample cell with windows that allow the IR light to pass through the gas sample. The Sensor Head is mounted on the sample cell, called the Airway Adapter. The Airway Adapter has a constant volume and path length as seen by the Sensor Head. The Sensor Head and Airway Adapter windows are chosen for their non-IR absorbing quality.

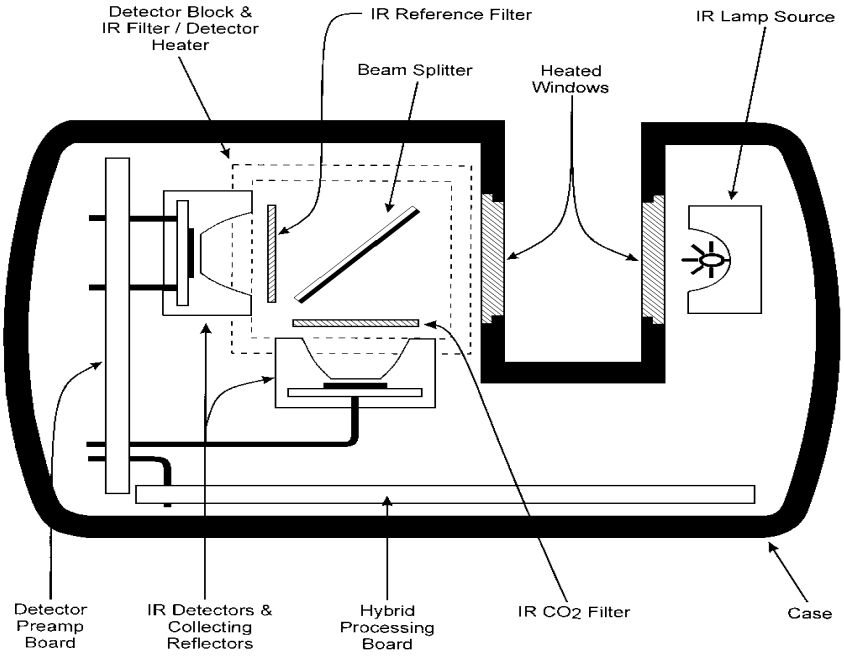
IR Filter: An optical bandpass filter is used to select a specific band of IR light centered on an exact wavelength. The optical IR filter's center wavelength is chosen for the specific gas to be measured (CO_2). The monitor also needs a reference channel which requires a second IR filter.

IR Detector: A lead selenide IR detector converts the IR light transmitted through the sample cell into an output voltage.



Sensor Head Components

The diagram below represents the components of the Sensor Head.



Sensor Head Case – The Sensor Head Case is sealed to control internal ambient CO_2 concentration and to provide sufficient moisture resistance for cleaning.

Hybrid Processing Board – The Hybrid Processing Board includes programmed control of:

- Lamp Power on/off
- Window Heating and Temperature Monitoring
- Detector Block Heating and Temperature Monitoring
- Multiplexing of Analog Signals
- Non-Volatile Memory containing all unit-specific data
- Bi-directional Digital Communications with the Signal Processing Board

Lamp and Reflector Assembly – The lamp is pulsed on and off. Its collimated light beam travels through one Sensor Head Window, through the Airway Adapter containing the patient sample, through the second Sensor Head Window, and through the beam splitter.

Heated Windows – The Sensor Head Windows are heated to reduce condensation. A thermistor monitors window temperature.

Beam Splitter – The Beam Splitter directs part of the light falling on it to the CO_2 IR Detector and the balance of the light to the Reference Channel Detector.

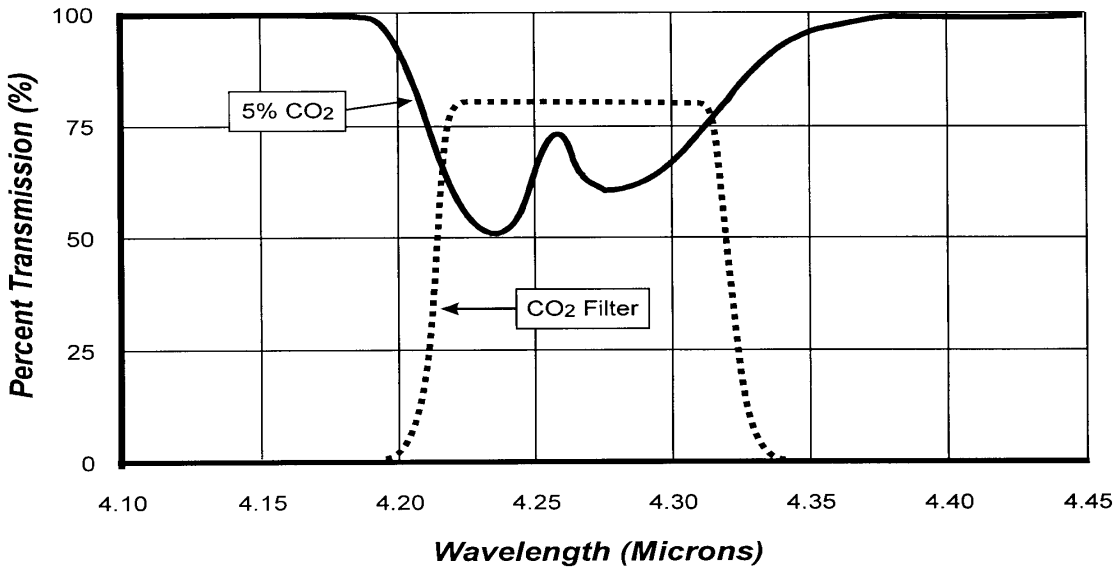
IR Filters – An optical band pass filter is located in front of both IR Detectors. Each filter passes to its detector only the wavelength of light that is appropriate.

IR Detectors – The IR Detectors convert the light falling on them into analog signals. The CO_2 IR Detector's output is relative to the CO_2 concentration in the Airway Adapter, while the reference channel IR Detector is insensitive to CO_2 concentration.

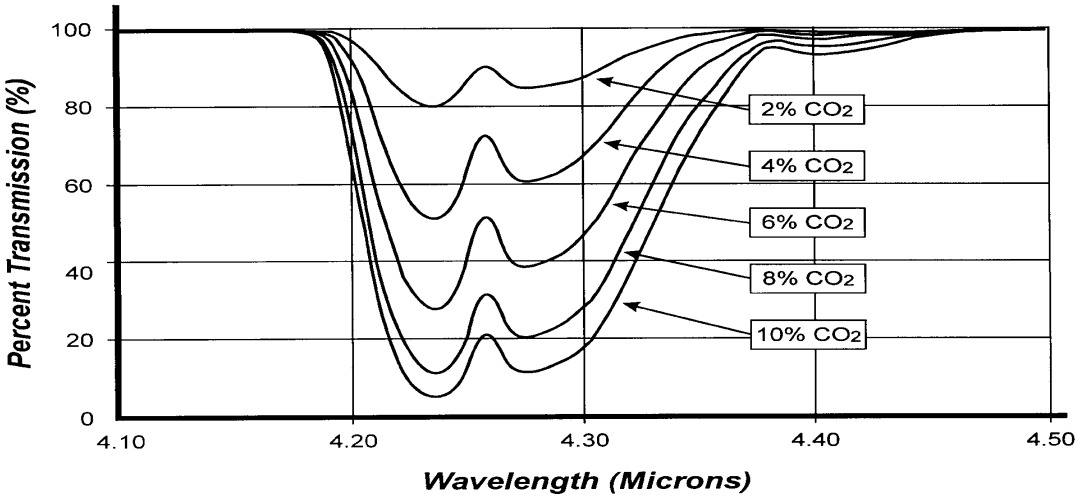
Detector Preamplifier Board – The outputs of the IR Detectors are amplified and filtered. These analog signals are fed through the Hybrid Processing Board's multiplexer to the Signal Processing Board.

Heated Detector Block – The Detector Block is heated to stabilize the IR filter temperature. A thermistor monitors Detector Block temperature.

To demonstrate the absorption of specific IR wavelengths by CO_2 gas, the chart below shows the amount of IR transmission for various wavelengths of IR light through CO_2. The CO_2 filter passes infrared light in the range between 4.22 and 4.32 microns.



The chart below shows that as the CO_2 concentration increases from 2% to 10%, infrared light transmission decreases. IR light transmission is inversely proportional to the IR light absorption of the gas. By measuring how much light gets through the sample gas and the CO_2 optical filter, we can calculate how much CO_2 is present in the gas sample.



Complications of NonDispersive InfraRed (NDIR) Monitoring

IR Light Amplitude Changes – Changes in the output of the IR light source directly affect the IR detector's voltage output for a given gas sample.

In this monitor, the IR lamp pulses on and off. The on phase is created by a constant voltage, providing a consistent light output. A consistent IR lamp output is more important than a specific output level.

Short and long term IR lamp amplitude changes are compensated for by use of a reference channel. A reference channel output change can be assumed to be non-gas related, and common to the CO_2 channel. Software data processing compensates for IR lamp output changes. This same mechanism compensates for any other common mode source of signal degradation, such as light beam obscuration by patient secretions.

Sample Gas Pressure Changes – Because a change in gas pressure in the Airway Adapter reduces the number of CO_2 molecules in the IR path, without airway adapter pressure compensation, changes in gas pressure would appear as changes in CO_2 concentration.

Typically, the monitor measures CO_2 only during the patient's expired breath phase. At this time, airway adapter pressure is very close to local barometric pressure. The sensors are factory characterized and calibrated at sea level where local barometric pressure, and airway adapter pressure is 760 Torr. The system also has the ability to set the local barometric pressure into the monitor. The Sensor Head stores this pressure value and uses it to correct for the difference in airway adapter pressure between calibration time and normal use.

Temperature Changes – Changes in the temperature of the IR filters, IR detectors, or sample gas (patient breath or calibration gas) directly affect the IR detector's voltage output for a given gas sample. Each of these must be either held at a constant temperature or monitored for temperature compensation.

During the expired phase, the patient's breath is slightly lower than body temperature (about 34°C). This relatively constant temperature relieves the monitor of the need to control sample gas temperature or correct for its changes.

Changes in sample gas flow rate can cause small sample gas temperature changes. The sensors are factory characterized and calibrated at 4.0 liters per minute.

NOTE: When using bottled calibration gas for span calibration or troubleshooting, its temperature might not be 34°C. The difference between calibration gas temperature and 34°C can cause CO_2 measurement errors.

The IR filters and detectors are mounted on the Sensor Head's detector block. Attached to the detector block is a thermoelectric heater strip and a thermistor. The heater temperature holds the Detector Block, IR Filters, and IR Detectors at a constant temperature (approximately 43°C).

Multiple IR Absorbing Gases – N_2O, water vapor, and anesthetic agents also absorb IR light and might be present in some applications. Each of these gases has different IR absorption characteristics, and choosing the correct CO_2 and reference channel IR filters reduces the "cross gas interference" effect.

Non-IR Absorbing Gases Present – The sample gas might also contain O_2, N_2O, or N_2. Although O_2 and N_2 don't absorb IR, they can create NDIR measurement problems via "collision line broadening."

The monitor uses assumed values for O_2 and N_2O and uses these values to compensate for "collision line broadening." The default values are 21.0% O_2 and 0.0% N_2O. Different values can be entered and stored in the Sensor Head.

NOTE: When using a calibration gas for span calibration or troubleshooting, O_2 and N_2O concentrations must also be entered.

Zero Baseline and Span Calibration – The voltage output of the IR Detector has no absolute meaning until it is established what CO_2 detector voltage represents 0.00% CO_2 gas concentration and what other voltage represents full scale CO_2 gas concentration (10.00%).

The voltage level when the IR Lamp is off, known as the "dark level," is the minimum voltage output of the IR Detector, and is used as the common reference for measuring all other IR Detector output voltages. When there is 0% CO_2 in the sample gas, there is minimum IR absorption, and therefore, maximum IR transmission. This measurement is the maximum output voltage of the IR Detector, and is stored in the system at each Zero Calibration. All CO_2 measurements are between these two values. The factory characterization of each unit includes the calculation of the system's CO_2 response curve. A field Span Calibration calculates simple multipliers that allow correction of long term component performance changes.

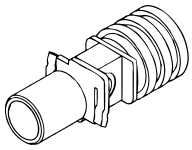
Nonlinearity – As the IR Detector output voltage decreases with increasing CO_2 gas concentration, some nonlinearities of NDIR technology must be managed.

The nonlinearity of the system's response curves was determined during its development. This nonlinearity is described in the resident CO_2 response curve, and is automatically compensated for during data processing.

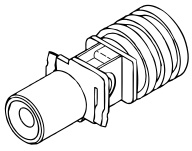
Preparation for Monitoring

Choosing an Airway Adapter

Select one of the two Airway Adapters that are available. Use the Adult Airway Adapter for monitoring patients with endotracheal tube sizes greater than 4 cc. The Adult Airway Adapter is shown below.



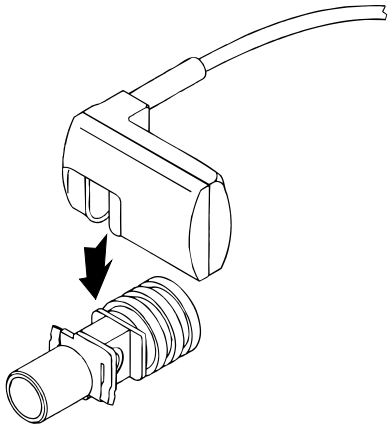
Use the Pediatric/Neonatal Airway Adapter for all other patients. The Pediatric/Neonatal Airway Adapter is shown below.



Zeroing the Airway Adapter

This procedure should be done at the start of monitoring or any time the message ZERO SENSOR is displayed on the monitor.

1. Insert the Airway Adapter into the Sensor as shown below.



2. Press the **PATIENT SETUP** key on the monitor to display the Main Menu, then select [RESP] so that CO_2 is displayed.

3. Make sure that the Airway Adapter is exposed to room air and is *not* in the patient breathing circuit. Keep the Sensor and Airway Adapter away from all sources of CO_2, such as ventilator exhaust and your own breath.

4. Select [ZERO SENSOR].

5. After approximately 15 seconds, the message ZERO OK appears on the display.

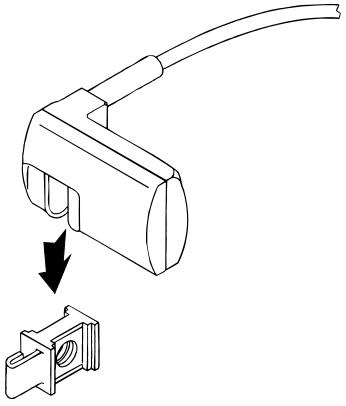
   If an error message is displayed, either the Airway Adapter windows are occluded or the Sensor is defective. Replace the Airway Adapter and repeat the zeroing procedure.

6. Press the **EXIT** key to return to the normal display.

Checking Sensor Calibration

1. Allow the sensor temperature to stabilize.

2. Place the sensor on the Span Check Cell attached to the sensor cable as shown below. Make sure that the sensor is fully seated on the cell.



3. Press the **PATIENT SETUP** key on the monitor to display the Main Menu, then select [RESP] so that CO_2 is displayed.

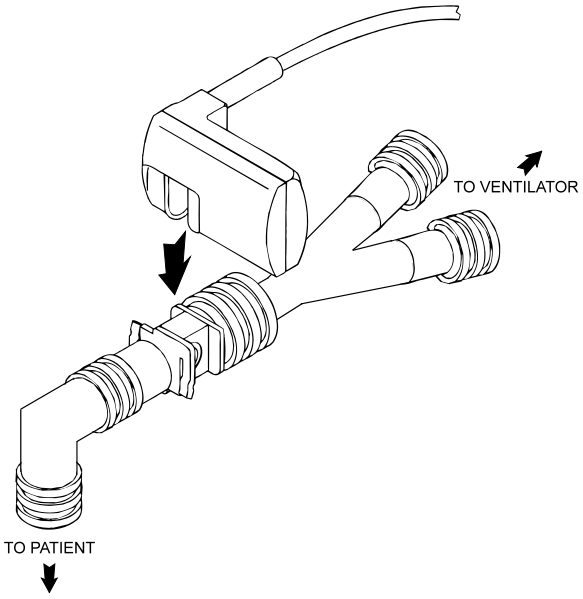
4. Select [CHECK SPAN]. The test takes approximately 15 seconds.

   The message SPAN OK appears on the display. If SPAN FAIL appears, do not use the sensor. Have the sensor checked and calibrated by a biomedical engineer or contact Ivy Biomedical Systems, Inc.

5. Press the **EXIT** to return to the normal display.

The Patient Airway Connection

1. Install the Sensor/Airway Adapter into the patient airway at the proximal end of the airway circuit between the endotracheal tube and the ventilator circuit wye. The Sensor cable should face away from the patient.



2. Connect the Sensor cable connector to the **$ETCO_2$** input on the monitor.

3. Verify the presence of a CO_2 waveform on the monitor.

Response Setting

Three response settings are available on the Model 450C monitor, slow, fast, or normal. Use the following procedure to set the response.

1. Press the **PATIENT SETUP** key on the monitor to display the Main Menu, select [RESP/CO_2], then select [RESP] so that CO_2 menu is displayed.

2. Select [SETTINGS] to display next menu, then select [NEXT SETTING] until Response is shown.

3. Select [RESPONSE] until the desired response setting is displayed.

4. Press the **EXIT** key to return to the normal display.

Compensation Settings

As described earlier in this section, settings are available for entering barometric pressure. N_2O, and O_2 in case the actual values differ from the default settings, which were entered into the Sensor at the factory. Default settings are barometric pressure = 760 Torr, N_2O = 0.0%, and O_2 = 21.0%. If necessary, use the following procedures to change these settings.

Barometric Pressure

1. Press the **PATIENT SETUP** key on the monitor to display the Main Menu, select [RESP/CO_2], then select [RESP] so that CO_2 menu is displayed. Then select [SETTINGS].

2. Use the [BAR PRESS ⇧ and ⇩] selections to set the barometric pressure to the desired value.

3. To return to the default setting (760 Torr) select [DEFAULT].

4. Press the **EXIT** key to return to the normal display.

N_2O Compensation

1. Press the **PATIENT SETUP** key on the monitor to display the Main Menu, select [RESP/CO_2], then select [RESP] so that CO_2 menu is displayed. Then select [SETTINGS].

2. Select [NEXT SETTING] until N_2O is displayed.

3. Use the [N_2O ⇧ and ⇩] selections to set the N_2O to the desired value.

4. Press the **EXIT** key to return to the normal display.

O_2 Compensation

1. Press the **PATIENT SETUP** key on the monitor to display the Main Menu, select [RESP/CO_2], then select [RESP] so that CO_2 menu is displayed. Then select [SETTINGS].

2. Select [NEXT SETTING] until O_2 is displayed.

3. Use the [O_2 ⇧ and ⇩] selections to set the O_2 to the desired value.

4. Press the **EXIT** key to return to the normal display.

Trace Scale Setting

Two trace scale settings are available for waveform display, 0 to 50 and 0 to 100. Use the following procedure to set the trace scale.

1. Press the **PATIENT SETUP** key on the monitor to display the Main Menu, select [RESP/CO_2], then select [RESP] so that CO_2 menu is displayed. Then select [SETTINGS].

2. Use the [TRACE SCALE] selection to select the desired trace scale setting.

3. Press the **EXIT** key to return to the normal display.

CO_2 Alarm Limits

1. Press the **ALARM SETUP** key to display the alarm limits menu.

2. If necessary select [PARAMETER] until $ETCO_2$ is displayed.

3. Use the [HIGH ⇧ and ⇩] selections to set the high CO_2 limit.

4. Use the [LOW ⇧ and ⇩] selections to set the low CO_2 limit.

   Each time you press a key, the corresponding limit changes by 2 Torr. The current settings are shown on the display when the front panel DISPLAY LIMITS selection is on.

5. Press **EXIT** to return to the normal display.

Respiration Rate Alarm Limits

1. Press the **ALARM SETUP** key to display the alarm limits menu.

2. Use the [PARAMETER] selection to display respiration rate (RR) limit settings.

3. Use the [HIGH ⇧ and ⇩] selections to set the high respiration rate limit.

4. Use the [LOW ⇧ and ⇩] selections to set the low respiration rate limit.

5. Press **EXIT** to return to the normal display.

Respiration On/Off

1. Press the **PATIENT SETUP** key to display the main menu. Select [RESP/CO_2], then select [RESP] to set respiration to OFF.

2. Press **EXIT** to return to the normal display.

Gas Calibration

The Sensor should never need to be calibrated. However, if hospital regulations require a periodic calibration, use the following procedure.

1. Make sure the Sensor has been operating for at least 30 minutes with no error conditions reported.

2. Zero the Sensor on an Adult Airway Adapter. See “Zeroing the Sensor” earlier in this section.

3. Press the **PATIENT SETUP** key on the monitor to display the Main Menu, select [RESP/CO_2], then select [RESP] so that CO_2 menu is displayed. The select [SETTINGS].

4. Select [TRACE SCALE] and press **TEST** at the same time to display a “hidden” menu.

5. Introduce a 1.0 ±0.1 liter per minute flow of 5% ±0.1% CO_2 balance Nitrogen into the Airway Adapter. The calibration gas should be held at a constant 34°C ±3°C. The flow of gas out of the Airway Adapter must be free and unobstructed. The reading should be 38 ±2 Torr. If 10% ±0.1% CO_2 balance Nitrogen is available, check the accuracy with this. The reading should be 76 ±3 Torr.

6. Press the **EXIT** key to return to the normal display.

INVASIVE PRESSURE MONITORING

Model 450C monitors configured for invasive pressure monitoring have two channels available for monitoring pressure. Procedures and specifications are the same for both channels. These procedures refer primarily to P1, which uses the **PRESS 1** connector (the lower pressure connector). Text in parentheses ( ) refers to P2.

Pressure Transducer

To ensure conformance with all safety and performance specifications, use only the recommended pressure transducers and cable. These are available from Ivy Biomedical Systems. Transducers are not to be immersed in liquid unless disconnected from the monitor.

WARNING: Disposable transducers are for single use only. Do not attempt to re-use these products.

WARNING: Disposable transducers and accessories identified as STERILE shall be handled in accordance to the manufacturer's instructions.

Connecting the Transducer

1. Connect the pressure cable to the **PRESS 1 (PRESS 2)** connector on the monitor's side panel.

2. Make sure that the catheter tip is at the same height as the dome of the pressure transducer during both zeroing and monitoring.

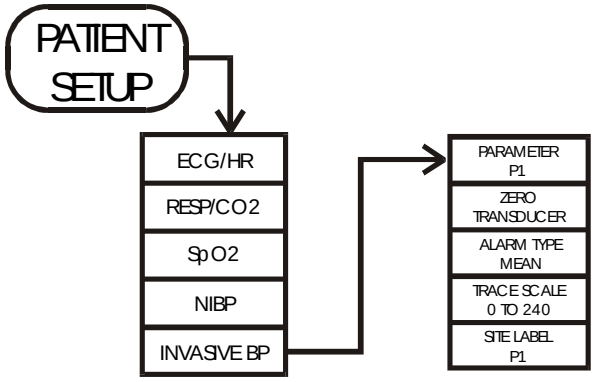
3. If a continuous flow catheter flush system is used, fill the transducer dome and set the transducer at the desired level before zeroing.

4. Always do a final zeroing of the transducer after it is connected to the fluid system, positioned, and allowed to stabilize for a few minutes.

5. Always follow the instructions that come with the pressure transducer to ensure proper calibration and operation.

Zeroing the Transducer

If the pressure transducer has not been zeroed, the monitor displays the message **ZERO TRANSDUCER**. Use the following procedure to zero the transducer. See the menu diagram below.



1. Vent the pressure transducer to air

2. Press the **PATIENT SETUP** key to display the main menu. Select [INVASIVE BP] to display the pressure select menu.

3. Use the [PARAMETER] selection to select P1 or P2 for the transducer being zeroed.

4. Select [ZERO TRANSDUCER] to zero the transducer.

   Once the system has been correctly zeroed, the **ZERO TRANSDUCER** message disappears.

   If the transducer has an offset greater than ±150 mmHg or a varying signal, the monitor does not zero the transducer, and a tone sounds when you select [ZERO TRANSDUCER].

4. Press **EXIT** to return to the normal display.

NOTE: If Barometric Pressure changes then the transducer must be zero again.

Blood Pressure Scale

1. Press the **PATIENT SETUP** key to display the main menu. Select [INVASIVE BP] to display the pressure select menu.

2. Use the [PARAMETER] selection to select P1 or P2 for the pressure channel being set.

3. Use the [TRACE SCALE] selection to select the scale. Selections are ±30, 60, 120, 240, and 300.

4. Press **EXIT** to return to the normal display.

Pressure Alarm Type

1. Press the **PATIENT SETUP** key to display the main menu. Select [INVASIVE BP] to display the pressure select menu.

2. Use the [PARAMETER] selection to select P1 or P2 for the pressure channel being set.

3. Use the [ALARM TYPE] selection to select the pressure to be used to trigger the blood pressure alarm. Selections are systolic (SYS), diastolic (DIAS), MEAN, and OFF.

4. Press **EXIT** to return to the normal display.

Pressure Alarm Limits

1. Press the **ALARM SETUP** key to display the alarm limits menu.

2. If necessary select [PARAMETER] to display P1 or P2 limits. If the alarm for P1 or P2 has been set to off, that selection does not appear in the [PARAMETER] selections.

3. Use the [HIGH ⇧ and ⇩] selections to set the high blood pressure limit.

4. Use the [LOW ⇧ and ⇩] selections to set the low blood pressure limit.

   Each time you press a key, the corresponding limit changes by 2 mmHg. The current settings are shown on the display when the front panel DISPLAY LIMITS selection is on.

5. Press **EXIT** to return to the normal display.

Expanded Pressure Scale

Use the following procedure to display one or both pressure waveforms on an expanded scale in Zones 3 and 4.

1. Press the **SYSTEM SETUP** key to display the mode menu. Then select [DISPLAY SETUP].

2. Use the [ZONE 4] selection to select expanded pressure display. Selections are Zones 3 and 4 expanded P1, Zones 3 and 4 expanded P2, and Zones 3 and 4 expanded P1/P2.

3. Press **EXIT** to return to the normal display.

Alternate Pressure Site Labeling and Automatic Scale/Limit Adjustment Feature (If present)

NOTE: This feature must be enabled by setting the **Pressure Site Labels** option in the **Configuration Menu** (see service manual) to **Present**. When enabled, the user may select alternate labels by using the SITE LABELING soft key in the **Invasive Pressure Setup** menu.

Labels for invasive blood pressures (P1 and P2) may be changed to one of several alternate labels at the users discretion.

Site label selections for P1 are: **P1, ART1, CVP1, PA1, ICP1, UAC1**, and **UVC1.**

Site label selections for P2 are: **P2, ART2, CVP2, PA2, ICP2, UAC2** and **UVC2**.

These labels will appear on both the screen, and the chart recorder printouts.

When a pressure site label is changed, the alarm limits are also automatically adjusted to reflect that change. Limits are stored separately for each site label.

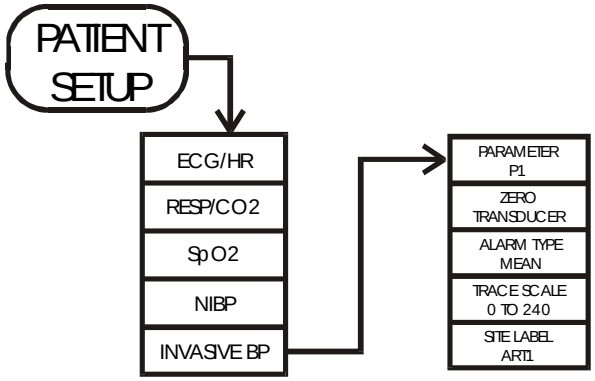
The default limits are as follows (channel 2 defaults are the same as the channel 1 defaults). Note that one set of invasive pressure alarm limits is stored regardless of whether Adult or Neonatal mode has been selected.

		SYS			DIAS			MEAN	
Site Label		**High**	**Low**		**High**	**Low**		**High**	**Low**
P1		150	80		100	50		120	60
ART1		150	80		100	50		120	60
CVP1		-10	10		-10	10		-10	10
PA1		150	80		100	50		120	60
ICP1		20	4		20	4		20	4
UAC1		100	40		60	20		70	30
UVC1		20	4		20	4		20	4

In addition, pressure scales for waveforms and trends are automatically adjusted whenever the user changes pressure site labels.

The default scale selections are as follows (again, P2 scales are the same choices as P1 scales):

Site Label	Scale
P1	0 to 240 mmHg
ART1	0 to 240 mmHg
CVP1	-30 to 30 mmHg
PA1	0 to 240 mmHg
ICP1	-30 to 30 mmHg
UAC1	0 to 120 mmHg
UVC1	0 to 60 mmHg



MASIMO SET® PULSE OXIMETRY MONITORING

Overview

Pulse oximetry allows you to continuously and no invasively monitor a patient's hemoglobin oxygen saturation. The oximetry sensor contains two light emitting diodes (LEDs) that transmit specific wavelengths of light, which are received by a photodetector.

Oxygen saturated blood absorbs light differently as compared to unsaturated blood. Thus the amount of light absorbed by blood can be used to calculate the ratio of oxygenated hemoglobin to total hemoglobin in arterial blood. The monitor displays this ratio as percent SpO_2. Normal values typically range from 95 to 100% at sea level.

Principles of Operation

The Model 450C Pulse Oximeter is based on three principles:

1. Oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry).

2. The volume of arterial blood in tissue and the light absorbed by the blood changes during the pulse (plethysmography).

3. Arterio-venous shunting is highly variable and that fluctuating absorbance by venous blood is a major component of noise during the pulse.

The Model 450C Pulse Oximeter as well as traditional pulse oximetry determines SpO_2 by passing red and infrared light into a capillary bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared light-emitting diodes (LEDs) in oximetry sensors serve as the light sources, a photodiode serves as the photodetector.

Traditional pulse oximetry assumes that all pulsations in the light absorbance signal are caused by oscillations in the arterial blood volume. This assumes that the blood flow in the region of the sensor passes entirely through the capillary bed rather than through any arterio-venous shunts. The traditional pulse oximeter calculates the ratio of pulsatile absorbance (AC) to the mean absorbance (DC) at each of two wavelengths, 660 nm and 940 nm.

$$S(660) = AC(660)/DC(660)$$

$$S(940) = AC(940)/DC(940)$$

The oximeter then calculates the ratio of these two arterial pulse-added absorbance signals:

$$R = S(660)/S(940)$$

The value of R is used to find the saturation SpO_2 in a look-up table built into the oximeter's software. The values in the look-up table are based upon human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia studies.

The Model 450C Pulse Oximeter assumes that arterio-venous shunting is highly variable and that fluctuating absorbance by venous blood is the major component of noise during the pulse. The Model 450C monitor decomposes S(660) and S(940) into an arterial signal plus a noise component and calculates the ratio of the arterial signals without the noise:

$S(660) = S1 + N1$

$S(940) = S2 + N2$

$R = S1/S2$

Again, R is the ratio of two arterial pulse-added absorbance signals and its value is used to find the saturation SpO_2 in an empirically derived equation into the oximeter's software. The values in the empirically derived equation are based upon human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia studies.

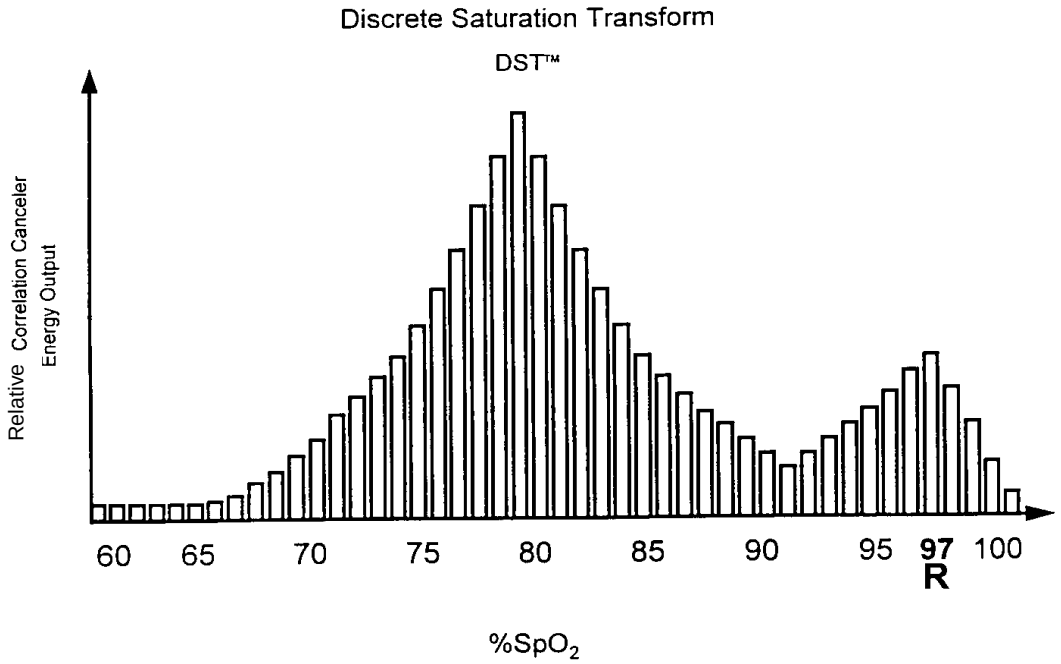
The above equations are combined and a noise reference (N') is determined:

$N' = S(660) - S(940) \times R$

If there is no noise N' =0; then $S(660) = S(940) \times R$ which is the same relationship for the traditional pulse oximeter.

The equation for the noise reference is based on the value of R, the value being seeked to determine the SpO_2. The Model 450C software sweeps through possible values of R that correspond to SpO_2 values between 1% and 100% and generates an N' value for each of these R values. The S(660) and S(940) signals are processed with each possible N' noise reference through an adaptive correlation canceller (ACC) which yields an output power for each possible value of R (i.e., each possible SpO_2 from 1% to 100%). The result is a Discrete Saturation Transform (DST™) plot of Relative output power versus possible SpO_2 value as shown in the following figure, where R corresponds to SpO_2 = 97%.

The red light power range is 1mw to 3 mw.
The infrared light power range is 0.7mw to 3mw.



The DST plot has two peaks: the peak corresponding to the higher saturation is selected as the SpO_2 value. This entire sequence is repeated once every two seconds on the most recent four seconds of raw data. The Model 450C SpO_2 therefore corresponds to a running average of arterial hemoglobin saturation that is updated every two seconds.

WARNING: The pulse oximeter should NOT be used as an apnea monitor.

WARNING: The pulse oximeter should be con~~sidered an~~ early warning device. If a trend towards patient deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's condition.

Caution: Use only sensors specified by Ivy Biomedical Systems, Inc. If you use sensors other than those manufactured by the Masimo corp., it might degrade performance and could damage the pulse oximeter.

Caution: Tissue damage can be caused by incorrect application or use of the sensor. Check the sensor site frequently. Do not allow the sensor to remain on one site for a prolonged period of time, especially when monitoring neonates. Refer to the sensor's specific instructions.

Caution: Never attach a SpO_2 sensor on a limb being monitored with a blood pressure cuff or a limb with restricted blood flow.

Caution: A poorly applied sensor might give incorrect saturation values. Reapply the sensor.

Caution: Choose a site with sufficient perfusion to ensure accurate oximetry values.

Caution: Certain nail aberrations, nail polish, fungus, etc. might give inaccurate oximetry values

Caution: Do not use the Model 450C Pulse Oximeter or sensors during Magnetic Resonance Imaging (MRI).

Pulse Oximetry Sensors

To ensure conformance with all safety and performance specifications, use only the recommended pulse oximetry sensors.

Monitoring Procedure

Use the following procedure for monitoring pulse oximetry:

1. Choose a site that is well perfused and provides proper alignment of the LEDs and receiving photodetector

   Select a site that has unrestricted blood flow

   Do not restrict blood flow when securing sensor with tape

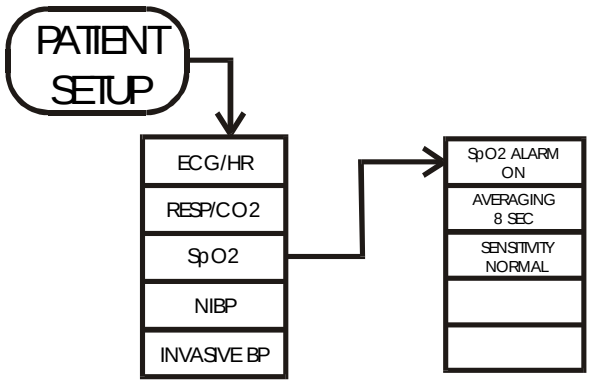
   Select an appropriate sensor and apply it to the patient, following the directions for use provided with the sensor

   Do not select a site near potential electrical interference (electrical cords, for example).

2. Connect the cable to the monitor's **SpO2** input.

3. Plug the sensor into the extension cable.

4. Use the procedures described in the following sections for alarm limit settings, response mode settings, and enabling or disabling the SpO2 alarm.



SpO_2 Alarm Limits

1. Press the **ALARM SETUP** key to display the alarm limits menu.

2. Use the [PARAMETER] selection to display SpO_2 % limit settings.

3. Use the [HIGH ⇧ and ⇩] selections to set the high SpO_2 % limit.

4. Use the [LOW ⇧ and ⇩] selections to set the low SpO_2 % limit.

   Each time you press a key, the corresponding limit changes by 1 %. The current settings are shown on the display when the front panel DISPLAY LIMITS selection is on.

5. Press **EXIT** to return to the normal display.

Response Mode Settings

1. Press **PATIENT SETUP** to display the menu. Select the [SpO_2] to display the SpO_2 menu..

2. Use the [SpO_2 ALARM] selection to set the Alarms on/off.

3. Use the [AVERAGING] selection to set the response time – 6, 8, 10, 12, 14 or 16 sec.

4. Use the [SENSITIVITY] selection to set the sensitivity level. (Options – Normal and High). The High sensitivity level should be used when the clinician wants to have absolute low perfusion performance of the Masimo SET® and is willing to sacrifice some sensor off detection capability.

5. Press **EXIT** to return to the normal display.

Default Values

The following defaults are set:

1. High SpO_2 limit – set to 100.

2. Low SpO_2 limit – set to 90.

3. Averaging – set to 8 sec.

4. Sensitivity – set to Normal.

Pulse Oximetry with ECG Off

When you are monitoring oxygen saturation but not ECG, set the ECG/HR menu setting to OFF to inhibit unwanted LEAD OFF alarms. With these settings, the heart rate on the display is derived from the pulse waveform and has a flashing pulse symbol for each detected heartbeat.

Use the following procedure to set ECG to OFF.

1. Press the **PATIENT SETUP** key to display the main menu. Select [ECG/HR] to display the ECG/HR menu.

2. Use the [ECG] selection to set ECG to off. When ECG is off, heart rate can be computed from the pleth waveform.

NOTE: To set heart rate limits when using any heart rate source, use the **ALARM SETUP** menus as described in the ECG Monitoring section of this manual.

Pulse Oximetry Considerations

If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs by alternate means and then check the Model 450C Pulse Oximeter for proper functioning.

NOTE: The waveform displayed by the SpO_2 signal is not proportional to the pulse volume.

Inaccurate measurements may be caused by:

- Incorrect sensor application or use
- Significant levels of dysfunctional hemoglobin (e.g., carboxyhemoglobin or methemoglobin) – see note.
- Intravascular dyes such as indocyanine green or methylene blue – see note.
- Exposure to excessive illumination, such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight (exposure to excessive illumination can be corrected by covering the sensor with a dark or opaque material)
- Excessive patient movement
- Venous pulsations
- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line

The Model 450C can be used during defibrillation, but the readings may be inaccurate for a short time.

Loss of pulse signal can occur in any of the following situations:

- The sensor is too tight
- There is excessive illumination from light sources such as a surgical lamp, a bilirubin lamp or sunlight
- A blood pressure cuff is inflated on the same extremity as the one with a SpO2 sensor attached
- The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia
- There is arterial occlusion proximal to the sensor
- The patient is in cardiac arrest or is in shock

NOTE: A pulse oximeter measures functional hemoglobin saturation. This is different to an arterial blood gas that measures fractional hemoglobin saturation. Differences can occur when significant levels of HbCO (carboxyhemoglobin), HbMET (methomoglobin) indocynanine green or methylene blue exist.

NIBP MONITORING

General Description

The Model 450C uses the oscillometric method for measuring non-invasive blood pressure (NIBP). The monitor automatically inflates and then slowly deflates the pressure cuff. Pressure fluctuations from the arterial pulse are detected by the monitor and used to determine the systolic, diastolic, and mean pressure. The monitor displays numeric values for this measurement on the left side of the monitor. No waveform is displayed.

For proper NIBP monitoring, use the accessories listed in the Accessories section of this manual.

NIBP has three modes of operation: manual, automatic, and stat. Press the CYCLE key to set the desired mode. In manual mode, a single measurement is taken by pressing the **START** key. Automatic mode generates measurements at regular intervals until the **STOP** key is pressed. Intervals are programmable for 1, 2, 3, 4, 5, 10, 15, 20, 30, or 60 minutes.

In STAT mode, pressing the **START** key initiates a series of measurements taken for a five-minute period.

A tabular display shows data as it is measured at the time of each NIBP reading. The display contains columns for time of day; systolic, diastolic, and mean NIBP; peripheral pulse measured from the NIBP cuff; respiration rate; SaO_2; invasive blood pressures and temperature. The latest four readings are displayed, and a scrolling procedure allows you to display previous readings.

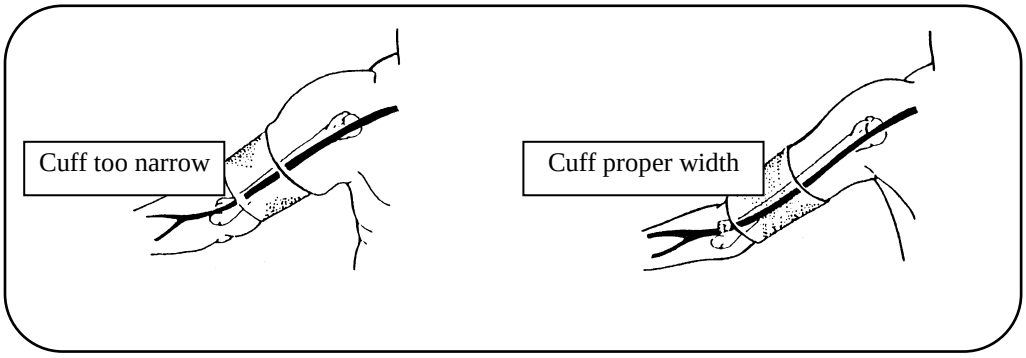
NIBP Monitoring Considerations

- Do not use this device on a patient who has an artificial heart or lung.
- Measurement might be impossible in case of continuous noise or when the patient's pulse is highly irregular.
- When this device is used to measure the blood pressure of critically conditioned patients, the pressures should be measured again by stethoscope or palpation if the indicated values are doubted.
- Since the pulse rate is measured at a distal part of the body, it might be different from the rate computed from the ECG.
- Use of the correct size cuff and proper wrapping help ensure accurate measurements.
- Do not restrict or compress the external tubing.
- Compression of the cuff or hose can cause noise, which might interfere with the measurement.
- Try to keep the patient relaxed and quiet during the measurement. Muscle tension or talking can interfere with the measurement.
- Check to be sure that use of the equipment does not result in prolonged impairment of the circulation of the patient.
- The repeated use of the Short Term Automatic Mode (STAT MODE) for more than five minutes can caused tissue damaged.

Cuff Placement

Proper cuff size and placement are essential to assure accurate blood pressure measurement.

The American Heart Association recommends that cuff sizes should be at a length-to-width ratio of about 2:1, ensuring that if the bladder width is 40% of the arm circumference, the bladder length will encircle 80% of the arm. Also, care should be taken to center the bladder directly over the brachial artery.



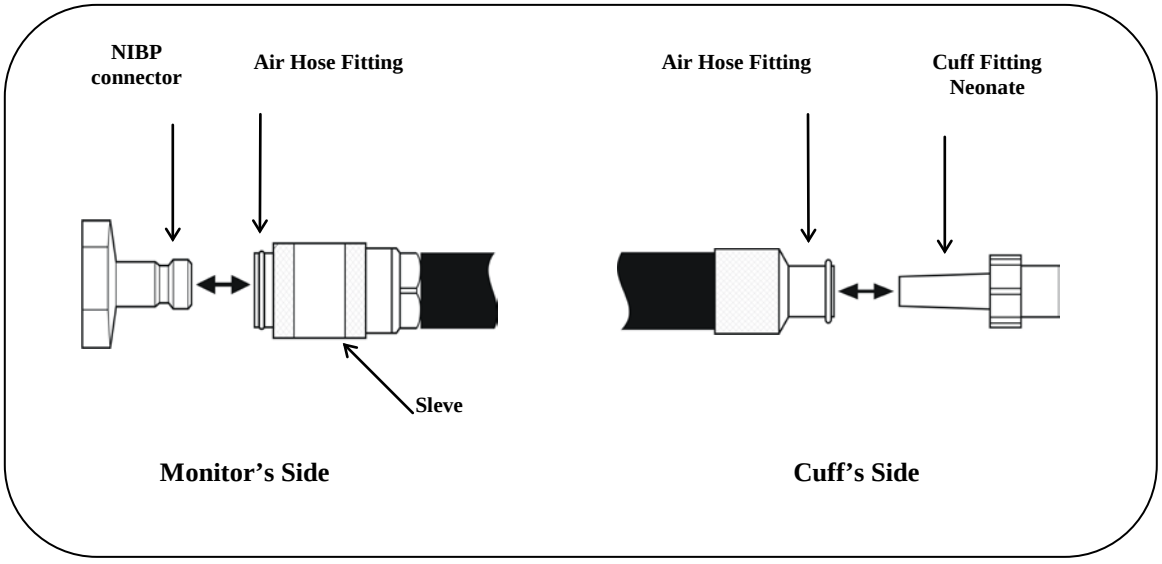
On the left, the bladder width is small for the arm, and full cuff pressure is never applied to the artery which can caused an erroneously high pressure result. On the right, the bladder width is adequate for the arm, and full cuff pressure is applied to the brachial artery.

Cuffs for thighs are available for large patients or those where neither arm is available for cuff placement. Blood pressure measured at the thigh is typically 20-30 mmHg higher than blood pressure measured at the upper arm.

Monitoring Procedure

1. Connect the air hose fitting to the NIBP connector on the monitor's side panel. To remove move the sleve back and pull the air hose.

   Also connect the other end of the air hose to the cuff fitting.

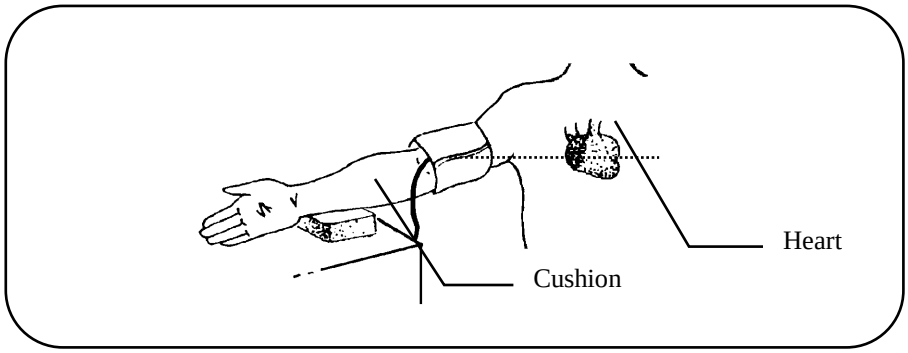


2. Apply the cuff to the patient as follows.

- Wrap the cuff snugly, with room between the cuff and arm for two fingers. If the cuff is wrapped too loosely, it cannot be inflated properly causing possible errors in measured values.

- Wrap the bare arm when possible. If clothing oppresses the arm, measured values might not be reliable.

  The end of the cuff should fall inside the range marked on the inside of the cuff. If it doesn't, use a different size cuff.



- Keep the cuffed part of the arm at the same level as the heart. If it is above the level of the heart the blood pressure measurement will be lowered. If it is below the heart level, the blood pressure will be raised (due to the physical weight of the blood).

- Do not compress the cuff or the rubber hose externally. Compression of the cuff or the rubber hose will cause measurement error. Rest the arm on a cushion to prevent compression against the body.

- Keep the patient as still as possible during the measurement.

WARNING: Always check the mode setting before starting an NIBP procedure. Monitoring a neonate in adult mode can cause injury to the patient.

3. Select the NIBP monitoring mode as described in the following procedures.

4. Press the **START** key to initiate measurements.

5. Press **STOP/DEFLATE** to deflate the cuff and end all NIBP procedures.

If the monitor cannot obtain a valid reading in manual mode, it displays a small number **1** near the NIBP mean value display and repeats the measurement. The monitor might try up to four measurements, depending on the problem, until a valid reading is obtained, displaying the number of tries after each measurement.

After several unsuccessful tries, the monitor cancels the measurement and displays the CHK CUFF alarm message.

NIBP Graph

To display the NIBP graph, press the **PATIENT SETUP** key, select [NIBP], and select [DATA FORMAT] until it is set at GRAPH.

The oscillation profile assists the clinician in determining the validity of the NIBP measurement. An erratic or flat profile suggests that excessive motion or other artifact may have affected the measurement. A profile shaped like a bell curve represents a measurement not affected by motion or other artifact.

NIBP Messages

If the monitor detects any problems with the measurement, one of the following messages is displayed. In most cases, the monitor attempts to get a good reading several times before displaying the message. The number of attempts is displayed near the NIBP readings.

Alarm Messages

CHECK CUFF:	Check the cuff and hose connector for leaks. Check for patient movement and check the cuff for proper attachment.
MOTION ARTIFACT:	Check for patient movement.
LOW INFLATION:	Check for insufficient monitor pressure because of high blood pressure.
ABNORMAL PULSE:	Check for patient movement or arrhythmic patient.
TIME EXCEEDED:	Check the cause of obstructed air discharge, such as patient movement or bent or crimped hose.
HIGH PULSE RATE:	Check the cause of obstructed air discharge, such as patient movement or bent or crimped hose.
OVER PRESSURE:	Check for folded arm of patient or bent hose.
WEAK PULSE:	Check for improper attachment of cuff.
CHECK CUFF HOSE:	Check for improper cuff or improper attachment of cuff.
CHECK CUFF SIZE:	Check for neonatal cuff being used in ADULT mode.

Non-Alarm Messages

PRESS START:	Indicates that you must press the NIBP START key to resume measurements.
MVT (movement):	Indicates that the monitor detected some patient movement during the measurement and the readings might be less reliable.
INOPERABLE:	The monitor has detected an NIBP failure.

Tabular Scrolling

Use the following procedure to scroll the tabular display to view previous readings.

1. Press the **PATIENT SETUP** key and select [NIBP] to display the NIBP menu.
2. Select [SCROLL ⇧] to scroll back or [SCROLL ⇩] to scroll forward until the desired readings are displayed.
3. Press **EXIT** to return to normal display. The data selected remains on the display until the next NIBP reading or until the scrolling procedure is repeated.

Clear Tabular Data

Use the following procedure to delete all tabular data in memory without turning power off.

1. Press the **SYSTEM SETUP** key then select [TREND SETUP].
2. Select [CLEAR TRENDS] to delete all trend data in the monitor, including tabular data.
3. Select [CONFIRM] to proceed with clearing data or [CANCEL] to retain all data.

NIBP Mode Select

Press the **CYCLE** key in the front panel NIBP area repeatedly until the desired mode is displayed in the zone where NIBP values are displayed.

Available modes are 1, 2, 3, 4, 5, 10, 15, 20, 30, or 60 minute automatic cycles, STAT, and OFF (MANUAL).

NIBP Alarm Settings

You must select one of the NIBP values (systolic, diastolic, or mean) to be used to trigger the NIBP alarm and then set up upper and lower alarm limits.

NOTE:When the monitor alarms, there is a delay of <0.3s to the signal output connector for remote equipment.

1. Press **PATIENT SETUP** then select [NIBP] to display the NIBP menu.
2. Use [ALARM TYPE] to select the pressure to be used to trigger the NIBP alarm. Selections are SYS (systolic). DIAS (diastolic), MEAN and OFF.
3. Press **EXIT** to return to the normal display.
4. Press **ALARM SETUP**.
5. Use the [PARAMETER] selection to select NIBP.
6. Use the [HIGH ⇧ and ⇩] selections to set the high NIBP limit.
7. Use the [LOW ⇧ and ⇩] selections to set the low NIBP limit.

   Each time you press a key, the corresponding limit changes by 2 mmHg. The current settings are shown on the display when the front panel DISPLAY LIMITS selection is on.
8. Press **EXIT** to return to the normal display.

NIBP Calibration

1. To enter the calibration mode, press **TEST**, **ALARM RESET**, and **START** at the same time.
2. Momentarily block the NIBP input and then attach the cuff to a manometer or other pressure measuring device.
3. Pump in pressure, and compare the manometer reading to the reading on the monitor display.
4. Press **STOP/DEFLATE** to exit the calibration mode.
5. With a cuff attached to the NIBP input, enter the calibration mode as described above. One minute after the monitor reaches a maximum pressure reading, leakage should be <5 mmHg/3 min.

TEMPERATURE MONITORING

Use only YSI Series 400 temperature probes or equivalent. Probes and cables are available from Ivy Biomedical Systems.

WARNING: Disposable probes are for single use only. Do not attempt to re-use these products.

1. Connect the temperature cable to one of the **TEMP** connectors on the monitor's side panel.

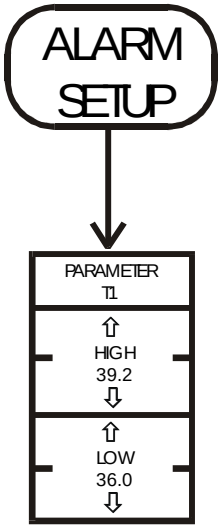
2. Locate the probe on the patient and wait for the probe temperature to stabilize.

   The temperature is displayed at the bottom of the screen. The label **T1** refers to **TEMP 1,** the connector to the left; the label **T2** refers to **TEMP 2.**

   When both temperature probes are connected to the monitor, the difference between the two temperatures (ΔT) is displayed in Zone 5.

Temperature Alarms Description

Alarm limits for each of the two temperature channels may be set via the **Alarm Setup** menu, in the same manner as setting other limits.
Temperature alarms may be set to off, (The default is off).
Temperature alarm messages appear in the alarm overflow area (lower left corner of the screen).
Temperature alarms are never latched, even if the latched alert option is enabled for other parameters.



ALARM MESSAGES

The following is a list of alarms and ranges for which they can be set. When the alarm triggers, the alarm indicator flashes on the display and the audio alarm tone sounds. Pressing **ALARM RESET** turns off any alarms that have triggered.

If the measurement returns to within the limits, the alarm turns off.

The **ALARM PAUSE** key disables the alarms for two minutes or until **ALARM PAUSE** is pressed again.

High heart rate: 15 to 300 bpm in 5 bpm increments

Low Heart Rate: 15 to 300 bpm in 5 bpm increments

High Resp Rate: 5 to 150 br/min in 5 br/min increments

Low Resp Rate: 5 to 150 br/min in 5 br/min increments

High $ETCO_2$: 10 to 100 Torr in 2 Torr increments

Low $ETCO_2$: 10 to 100 Torr in 2 Torr increments

NIBP High: Selectable systolic, diastolic, or mean 10 to 300 mmHg in 2 mmHg increments

NIBP Low: Selectable systolic, diastolic, or mean 10 to 300 mmHg in 2 mmHg increments

NOTE: For additional NIBP alarm conditions, see the NIBP Monitoring section of this manual.

IBP High: Selectable systolic, diastolic, or mean; -40 to 300 mmHg in 2 mmHg increments

IBP Low: Selectable systolic, diastolic, or mean; -40 to 300 mmHg in 2 mmHg increments

NOTE: Invasive and non-invasive pressures can be set to alarm on systolic, diastolic, or mean.

High SpO_2: 50 to 100%in 1% increments

Low SpO_2: 50 to 100% in 1% increments

Asystole: R-to-R interval >6 seconds

No Pulse: When triggering from pleth or invasive pressure, the interval between heartbeats exceeds six seconds

Lead Off: Detached lead or offset potential ≥0.5 V. This alarm is not reset by the **ALARM RESET** key

Check Leads: Electrode impedance is >4 kΩ

Coincidence: When QRS and respiration triggers are synchronized for eight consecutive events

Apnea: Absence of detectable respiration activity for 5, 10, 15, or 20 seconds, selectable

MONITOR TESTING

Press and hold the **TEST** key to test the internal functions of the monitor. You should do this each time you begin monitoring a patient.

The TEST function generates a 1 mV ECG pulse at 70 bpm, a respiration signal at 70 br/min and a coincidence check, which are displayed on the display and are available at the rear panel connector. The monitor also displays invasive pressure readings of 150/50 and temperature readings of 40°C. If these indications are not present, contact qualified service personnel.

To test the visual and audio alarms turn on the monitor and press the ALARM PAUSE key. Check that the LEAD OFF messages is displayed on the ECG channel and the audio alarm is on. While pressing the TEST key check for the following sequence to happen: 1) LEAD OFF message disappear, 2) Monitor starts counting QRS, 3) HR<40 message appears on ECG channel, audio alarm is triggered, 4) RR<10 message appears on ECG channel, audio alarm is triggered, 5) A few seconds after the HR<40 message disappeared, a COINCIDENCE message is displayed on the Respiration channel. Stop pressing the TEST key and press ALARM OFF, all audio alarms should be silenced and visual alarms should be displayed.

Under normal operation, no internal adjustment or recalibration is required. Safety tests and internal adjustments should be done by qualified personnel only. Safety checks should be performed at regular intervals or in accordance with local or governmental regulations. In the event that internal adjustment or recalibration is necessary, refer to the Operation and Maintenance Manual for this equipment.

Note:
If no display is visible on the monitor, the monitor is inoperable. Contact qualified personal. When ECG input is >0.5 V, a inoperable condition is indicated by flashing LEAD OFF indicator on the display.

MAINTENANCE AND CLEANING

The Monitor

When necessary, clean the exterior surfaces of the monitor with a cloth or swab dampened with a warm water and mild detergent solution. Do not allow liquids to enter the interior of the instrument.

CAUTION:

- Do not autoclave, pressure sterilize, or gas sterilize the monitor.
- Do not soak or immerse in any liquid.
- Use cleaning solution sparingly. Excessive solution can flow into the monitor and cause damage to internal components.
- Do not touch, press or rub the display and covers with abrasive cleaning compounds, instruments, brushes, rough surface materials, or bring them into contact with anything that could scratch the display or the covers.
- Do not use petroleum based or acetones solutions, or other harsh solvents, to clean the monitor.

Patient Cables

Do not autoclave the patient cables.

Wipe the cables using a mild detergent solution. Never submerge the cables in any liquid or allow liquids to enter the electrical connections.

Reusable Pressure Transducer

1. Remove the dome.
2. Clean the transducer as recommended by manufacturer.

CAUTION: Do not immerse any part of the electrical connector of the transducer in the cleaning solution at any time. Examine the outer sheath of the cable for perforations. If the outer covering is damaged in any way, do not immerse the cable in the cleaning solution; this might result in moisture entering the transducer case, which is vented through the cable.

WARNING: If liquids are permitted to enter the electrical connector, resistance between the electrical element and the transducer case should be checked to ensure that the leakage current is below acceptable levels for safe use on patients.

Cleaning and Reuse of SpO_2 Sensors

Reusable sensors can be cleaned as follows:

1. Remove the sensor from the patient.

2. Clean the sensor as recommended by the manufacturer.

NOTE: If the sensor fails to track the pulse consistently, the sensor might be incorrectly positioned. Reposition the sensor or choose a different monitoring site.

CAUTION: Do not soak or immerse the sensor in any liquid solution. Do not sterilize any sensor by irradiation, steam, or ethylene oxide.

Reusable Temperature Probes

Clean the probes as recommended by the manufacturer.

CAUTION: Probe plugs should *not* be immersed.

CAUTION: Never boil the temperature probe. Autoclaving might cause the insulation to fail, and might also cause the probe to give inaccurate readings.

$EtCO_2$ Sensor and Airway Adapters

The Sensor Head, Head Cables(s) and Airway Adapters should be cleaned as recommended by manufacturer.

CAUTION Do not immerse the Head or Cables in cleaning solution or any other liquids. The Sensor Head can not be sterilized.

Preventive Maintenance

ECG & RESP
Check that:
- Cables and Leads are clean and intact.
- The LEAD OFF message is displayed when the patient cable is connected, but the patient leads are not connected. Connecting the patient leads together should make the message disappear.

SpO2
Check that:
- Cables and Leads are clean and intact.
- The probe is functioning (place it on a finger).

Temperature
Check that:
- Temperature probe and cable are clean and intact.
- Both channels are working (connect a temperature probe).

Invasive Blood Pressure

Check that:

- Cables and pressure transducers are clean and intact.
- The device recognizes cable connection (activated on the display).
- The zeroing of transducers is working correctly.

Non Invasive Blood Pressure

Check that:

- The cuff and hose are clean and intact.
- A few seconds after turning the monitor on the message “PRESS START” appears in the NIBP zone.

EtCO2

Check that:

- The cable and sensor are clean and intact.
- The probe is functioning. Connect the sensor to the monitor and verify the light on the head of the sensor turns on and the “WARMING UP” messages is displayed on the screen.

ACCESSORIES

ECG/Respiration

Standard Three-Lead

Three-lead patient cable	590170
Patient leads	590162

Optional Five-Lead

Five-lead patient cable	590167
Patient leads	590168

NOTE: For proper respiration monitoring, cable capacitance between the RA and LA leads must be 400 ±100 pF.

For units used in Australia

Three-lead patient cable with 1kΩ series resistors	590197
Patient leads	590162
Five-lead patient cable with 1kΩ series resistors	590207
Patient leads	590168

$ETCO_2$

Adult Airway Adapter	590186
Pediatric/Neonatal Airway Adapter	590188
$ETCO_2$ Sensor with Span Chech and one Adult Airway Adapter	2315-00-01

Invasive Pressure

Pressure transducer reusable	590252
Cable for reusable pressure transducer	590251
Disposable transducer domes (Box of 50)	590253
Disposable pressure transducer (Box of 10)	590016
Cable for disposable pressure transducer	590235

Non-Invasive Pressure (NIBP)

Disposable Cuffs

Neonatal Cuff, bladderless (3–6 cm)	590239
Neonatal Cuff, bladderless (6–11 cm)	590240
Neonatal Cuff, bladderless (8–15 cm)	590241
Child Small Cuff, full bladder (13–20 cm)	590267
Adult Small Cuff, full bladder (18–26 cm)	590268
Adult Cuff, full bladder (26–35 cm)	590269

Reusable Cuffs

Infant Cuff (8–14 cm)	590270
Child Cuff (13–20 cm)	590271
Adult Small Cuff (18–26 cm)	590272
Adult Cuff (26–35 cm)	590273
Adult Large Cuff (32–42 cm)	590274
Adult Thigh Cuff (42–50)	590275

Cuff Hoses

For use with all disposable cuff (yellow hose).	2686-00-01
For use with all reusable cuffs (black hose).	2689-00-01

Temperature

Reusable temperature probe – rectal/esophageal	590003
Reusable temperature probe – skin	590005
Reusable cable for YSI disposable probes	590000
Disposable temperature probe YSI Series 400 or equivalent	590001
Disposable skin temperature probe	590002

Recorder

Recorder Paper, box of 10 rolls	590035

SpO_2 Reusable Sensors

Adult LNOP DC-1 Finger Sensor, Reusable	590227

SpO_2 Disposable Sensors

Neonatal LNOP-Neo, Disposable Sensor, Box of 20	590223
Pediatric LNOP-Pdt, Slender Digit Disposable Sensor, Box of 20	590222
Neonatal Pre-term LNOP-NeoPt, Disposable Sensor, Box of 20	590224
Adult LNOP-Adt, Disposable Sensor, Box of 20	590221

SpO_2 Patient Cables

Patient Cable, 8 ft PC08 with LNOP Sensor Connector	590220
Patient Cable 12 ft PC12 with LNOP Sensor Connector	590230

SpO_2 Starter Kits

Starter Kit with 2 LNOP-Adt and 2 LNOP-Pdt sensors, and 12’ PC12 sensor cable	590225
Starter Kit with 2 LNOP-Neo and 2 LNOP-NeoPt sensors, and 8’ PC08 sensor cable	590226
Starter Kit with Adult LNOP-DC1 finger sensor, reusable and PC08 sensor cable	590228

Disposal

Disposal of devices or consumables must be done in accordance with local, state, and federal laws and regulations.

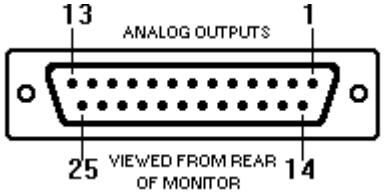
WEEE Directive 2002/96/EC.- Do not dispose of WEEE products in general waste. At the end of life of product contact IVY Biomedical Systems, Inc. customer service for return instructions.

REAR PANEL OUTPUTS

Analog Output Connector

Pin	Signal	Output
1	ECG X1000	1 V = 1 mV input 0.5 to 40 Hz filtered 0.05 to 100 Hz diagnostic (Adult Mode only)
2	ECG	Adult: X1000 (1 V = 1 mV input) Neonate: X2000 (1 V = 0.5 mV input)
3	RESPIRATION	2.5 V peat-to-peak maximum (±1.25 V), variable with front panel control
4	IBP1	10 mV/mmHg, 0 mmHg = 0 mV ±50 mV (after Auto-Zero)
5	IBP2	10 mV/mmHg, 0 mmHg = 0 mV ±50 mV (after Auto-Zero)
6	PLETH	Waveform, 1.2 V peak-to-peak maximum. No sensor = +0.6 V
7	HEART RATE	16.6 mV/bpm, 300 bpm max, 60 bpm = 1 V, 120 bpm = 2 V, 300 bpm = 5 V
8	SpO_2	50 mV/% SpO_2 100% max, 100% = 5 V
9	No Connection	
10	GROUND	Ground
11	$EtCO_2$	50 mV/mmHg 38mmHg = 1.90 ± 50 mV
12	ALARM OUT	High +5 V (>2.4 V) when an alarm is present
13	GRAPH OUT	Relay closure for remote recorder
14	GRAPH COM	
15	UNIT ON	
16	NURSE CALL	Relay closure for Nurse Call option
17	N.C. COMMON	
18	LEAD OFF ALARM	High +5 V (>2.4 V) when a lead off alarm is present
19-25	No Connection	

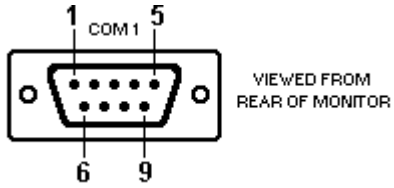
For the mating connector, use Ivy P/N 188505, 25-pin plug for 22-26 AWG wire. Use RFI/EMI shielded cable clamp, Ivy P/N 210032, 15-conductor shielded cable, Ivy P/N 600005, and a ferrite bead, Ivy P/N 150025, at the monitor end of the cable.



COM 1 & COM 2 Connectors

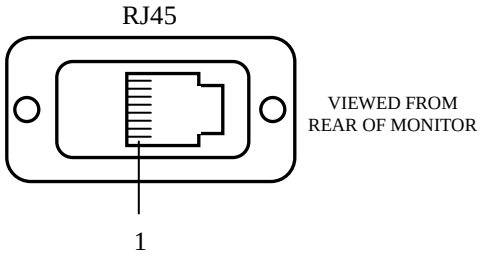
Pin	Signal	Output
1	No Connection	
2	RECEIVE DATA	Not Used
3	TRANSMIT DATA	RS-232 ±9 V (±5 V min.)
4	Not Used	
5	SIGNAL GROUND	Reference for COM 1 signals
6	Not Used	
7	REQUEST TO SEND	Not Used
8	CLEAR TO SEND	Not Used
9	Not Used	

For the mating connector, use Ivy P/N 179004, 9-pin receptacle for 22-26 AWG wire. Use RFI/EMI shielded cable clamp, Ivy P/N 210030, and 5-conductor shielded cable, Ivy P/N 600002.



RJ45 Connector (option in place of COM 2)

Pin	Signal
1	TRANSMIT DATA
2	SIGNAL GROUND
3	RECEIVE DATA
4	Not Used
5	Not Used
6	SIGNAL GROUND
7	Not Used
8	Not Used



Configuration Menu

To access the configuration menu hold both the TEST button and the EXIT button in while switching the power ON.
Use the arrow keys (⇑ ⇓) to scroll to the function to be changed.
Use the CHANGE OPTION key to select the desired option.

CAUTION: Configuration is carefully preset at the factory based on which parameters and options have been installed. Extreme care should be taken when altering any of these settings and all users should be informed of changes

Configuration Menu

FUNCTION	OPTIONS			
ECG	3 LEAD 60Hz	3 LEAD 50Hz	5 LEAD 60Hz	5 LEAD 50Hz
RESP	ABSENT	IMPEDANCE	CO_2	IMP + CO_2
SpO_2	ABSENT	NELLCOR MP204	MASIMO	NELLCOR MP405
NIBP	ABSENT	COLIN		
TEMP	ABSENT	SINGLE	DUAL	
INVASIVE BP	ABSENT	SINGLE	DUAL	
RECORDER	ABSENT	PRESENT		
COM 1	ABSENT	HTS820TC	HTS820	THERMALINK
COM2/ETHERNET	ABSENT	CPC REV C	ANSAR REV B	
AUDIO OFF FEATURE	ABSENT	PRESENT		
LATCHING ALARMS	ABSENT	PRESENT		
PRIORITY ALARMS	ABSENT	SCHEME 1	SCHEME 2	
INITIAL LIMITS	DEFAULTS	STORED		
TEMP UNITS	DEGREES F	DEGREES C		
PRESSURE UNITS	KPA	MMHG		
PRESSURE SITE LABELS	ABSENT	PRESENT		
CO_2 UNITS	KPA	MMHG	PERCENT	
ALARM TONE	3.0 KHZ	3.5KHZ	4.0KHZ	
TAB RETENTION	NONE	ONE HOUR	PERMANENT	TWO HOUR
DATE FORMAT	MM/DD/YYYY	DD/ MM/YYYY		
KEYPAD TYPE	17 KEYS	20 NO LIGHT	20 + LIGHT	

TESTING AND TROUBLESHOOTING

General

Press and hold the **TEST** key to test the internal functions of the monitor. You should do this each time you begin monitoring a patient.

The TEST function generates a 1 mV ECG pulse at 70 bpm, a respiration signal at 70 br/min and a coincidence check, which are displayed on the display and are available at the rear panel connector. The monitor also displays invasive pressure readings of 150/50 and temperature readings of 40°C. If these indications are not present, continue with troubleshooting procedures.

Under normal operation, no internal adjustment or recalibration is required. Safety tests and internal adjustments should be done by qualified personnel only. Safety checks should be performed at regular intervals or in accordance with local or governmental regulations.

ECG Test

Equipment Required

ECG Simulator (Fogg Model M310 or equivalent)

Initial Settings for the Test

HR high alarm limit	150
HR low alarm limit	50
Lead select	I
Filter	ON
ECG Size	10 mm/mV
Alarms	ON (ALARMS OFF message not displayed)

Test Procedure

1. Connect the patient cable and simulator to the monitor and set the simulator as follows:

   - Heart rate of 80 bpm
   - Amplitude of 1.0 mV

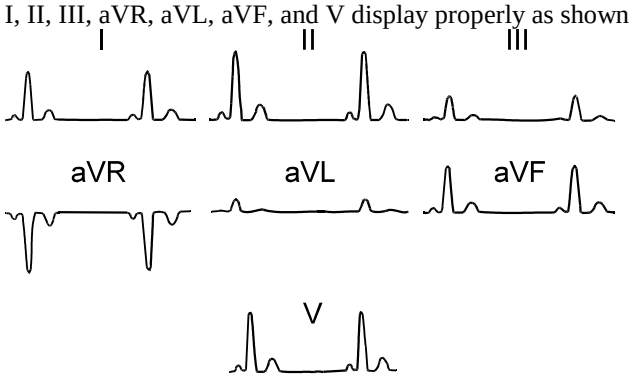
2. Observe the following on the monitor display:

   - ECG Lead I is displayed with an amplitude of approximately 10 mm and is noise free

     Press FREEZE to check the waveform if necessary.

   - Heart rate of 80 ±1 bpm
   - The heart next to the heart rate indicator flashes with every QRS complex displayed.

3. Verify that ECG Leads I, II, III, aVR, aVL, aVF, and V display properly as shown below.



4. Check the LEADS OFF alarm by removing one lead at a time from the simulator.

5. Change the heart rate on the simulator to 40 bpm. Notice the following:

   - The HR <50 message appears on the display.
   - Heart rate value of 40 ±1 bpm is displayed.

6. Press **ON/OFF**. Notice the following:

   - Audible alarm stops
   - Alarms Off message is displayed.

7. Press **ON/OFF**. The Alarms Off message goes off.

8. Set the simulator heart rate to 200 bpm. The HR >150 message is displayed, and an audible alarm sounds.

9. Set the simulator to 80 bpm.

Pressure Test

Equipment Required

Transducer Simulator (Fogg Model BP48C or equivalent)

Test Procedure

1. Press and hold the monitor's TEST button. The monitor's pressure reading should be 150/50.

2. Connect the simulator output to the monitor's pressure input.

3. Set the simulator output to 0 mmHg.

4. Zero the pressure channel.

5. Set the simulator to 100 mmHg output.

6. Set the monitor's blood pressure range to 120.

7. Check for the proper level on the monitor's display.

8. Repeat for the second pressure channel.

Respiration Test

Equipment Required

Respiration Simulator (Fogg Model M98 or equivalent)

Test Procedure

Connect the BLACK (LA) and RED (LL) leads to the black simulator terminal. Connect the WHITE (RA) lead to the white simulator terminal.

1. Set the monitor to NEONATAL mode and the front panel RESP SIZE to 50%.

2. Set the simulator as follows:

Power:	ON
Rate:	50 br/min
Variation:	0.5 Ω
Toggle Switch:	NORM.
Base Impedance:	1 kΩ

   The triggering should be consistent and the rate should be 50 ±1 br/min.

3. Set the monitor to ADULT mode. Check for the displayed amplitude to drop approximately 50%.

   The triggering should be consistent and the rate should be 50 ±1 br/min.

4. Turn the simulator power off. Set the APNEA DELAY to 20 seconds. The respiration must not trigger. Check for an APNEA alarm in 20 seconds.

Temperature Test

Equipment Required

Temperature Simulator (Fogg Model TP-69 or equivalent)

Test Procedure

1. Connect the SERIES 400 TEMPERATURE OUTPUT of the simulator to the monitor's TEMP input.

2. Set the output of the simulator to 37°C. The monitor's temperature reading should be 37°C ±0.1°C.

3. Check the monitor's output at 20°C and 40°C.

4. Repeat for the second temperature channel.

Pulse Oximeter Test

Equipment Required

Sensor with cable

Test Procedure

1. Connect the patient cable to the monitor and the sensor to your finger.

2. Check for waveform, SpO_2 reading, pulse rate, bar indicator, and audio tone.

$ETCO_2$ Test

Equipment Required

$EtCO_2$ sensor with cable.

Test Procedure

1. Make sure the $EtCO_2$ waveform is displayed in either zone 2, 3, or 4.
2. Check for the NO SENSOR message to be displayed.
3. Plug in the $EtCO_2$ sensor and place the airway adaptor on it. The sensor should illuminate and the display should indicate that the sensor is warm-up. Warm-up should conclude in 3-5 minutes.
4. Through the RESP/CO2 menu, zero the sensor and check for the ZERO OK message to be displayed.
5. Remove the airway adaptor from the sensor and make sure the OFF AIRWAY message is displayed.
6. Place the span check cell on the sensor. Through the RESP/CO2 menu run the SPAN CHECK test, and wait for the SPAN OK message.
7. With the span check cell still on the sensor, check for the $EtCO_2$ value and waveform to be within the percentage value of the Barometric Pressure (760mmHg) printed on the span check cell.
   (Span Check Value = %value * 760/100)

NIBP Test

Equipment Required

Cylinder, such as bottle or coffee can
NIBP cuff, hose, and Y-connector
Manometer or other pressure measuring device

Test Procedure

1. To enter the calibration mode, press **TEST**, **ALARM RESET**, and **START** at the same time.
2. Momentarily block the NIBP input and then attach the cuff to a manometer or other pressure measuring device.
3. Pump in pressure, and compare the manometer reading to the reading on the monitor display.
4. With a cuff attached to the NIBP input, enter the calibration mode as described above. One minute after the monitor reaches a maximum pressure reading, leakage should be <5 mmHg/3 min.

Recorder Test

Use the following procedure to verify that the recorder is operating properly.

1. Set the recorder to print ECG and respiration waveforms and set the recorder to TIMED mode.
2. Press **PRINT** and then press and hold the **TEST** key for at least 30 seconds.

The recorder prints waveforms that match the waveforms on the display. The recorder continues printing for 30 seconds and then stops.

Battery Test

1. Disconnect the power cord from the monitor so that it is operating on battery.

2. In approximately 30 seconds, the battery indicator should appear in the lower right corner of the display.

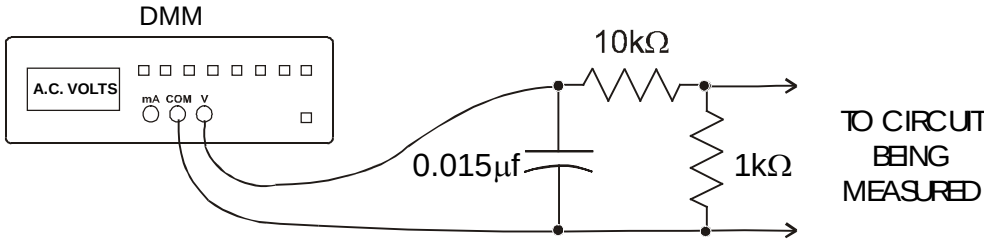
3. Connect the power cord. Verify that the charging light starts flashing (pre-charged qualification) and that after a few minutes either one of the following conditions occur: the charging light stays on (fast charging) or the charged led goes on (maintenance charging).

4. If the fault light goes on replace the battery immediately.

Isolation and Leakage Tests

Use a leakage tester or use the ac voltage range on a digital voltmeter to measure across a 1 kΩ resistor as shown below.

CAUTION: Be careful to connect the circuit below only between the measurement points indicated in the following instructions. Do *not* connect this circuit directly across line voltage. Full line voltage would damage the measurement circuit and could possibly damage the monitor and/or the digital voltmeter.



1. Measure between a known ground and the monitor's ground post on the rear panel. With the line cord properly grounded, with the ground removed, and with the line cord reversed, the readings should be <100 μA.

2. With the line cord grounded, measure between shorted patient leads and the hot side of the ac line. The reading should be <10 μA.

System Error Messages

Numeric messages might appear in the lower right corner of the display if the processor detects a problem with the monitor. If a message appears, contact Ivy Biomedical Systems Service Department.

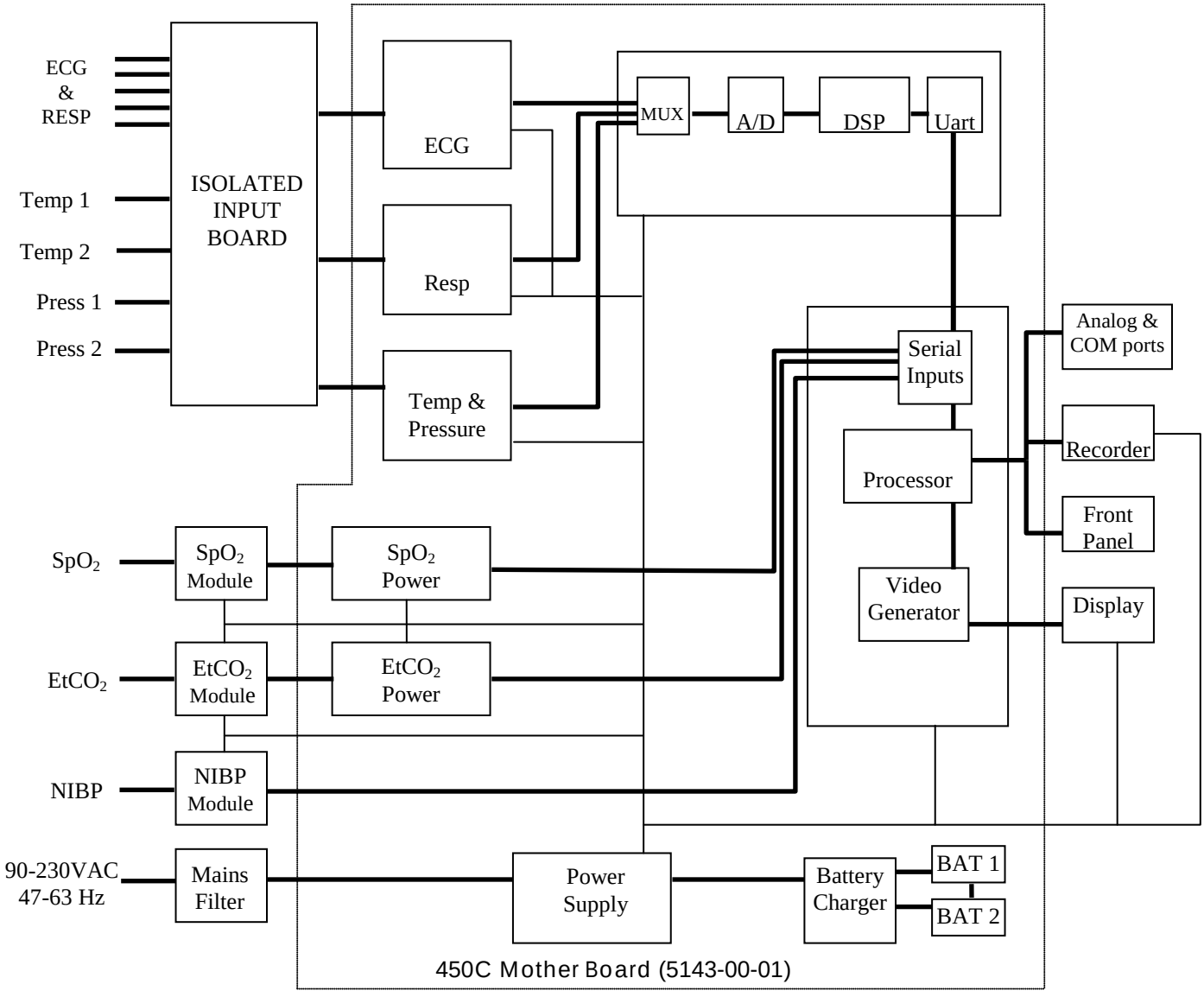
When you call, have the following information available:

Model Number
Serial Number
Numeric Error Message
Procedure being performed when the message appeared

System Error Messages & Solutions

Error	Meaning	Solution
1	The EPROM checksum test has failed.	Replace U57 (2600-00-04) on Mother Board (5143-00-01) board or replace U53 (2601-00-04) on Mother Board (5143-00-01) board or replace Mother Board (5143-00-01).
2	The static RAM test has failed.	Replace Mother Board (5143-00-01).
3	The non-volatile (clock chip) RAM test has failed.	Replace Lithium Battery (330115) or replace Mother Board (5143-00-01).
4	An undefined interrupt has been detected.	Replace Mother Board (5143-00-01)
5	A system timing error has been detected.	Replace Mother Board (5143-00-01)
6	No DSP data has been received.	Replace Mother Board (5143-00-01).
7	A DSP communication error (framing, overrun, etc) has been detected.	Replace Mother Board (5143-00-01)
8	Bad DSP data has been received (ie: a bad header byte).	Replace Mother Board (5143-00-01)
9	An unknown error has been detected.	Replace Mother Board (5143-00-01)

Simplified Block Diagram



REPLACEMENT PARTS

Printed Circuit Boards

Part	Ivy Part Number
450C Monitor Mother Board	5143-00-01
Isolated Input Board (ECG/RESP, 2Temps & 2Press)	5144-00-01
Isolated Input Board (ECG/RESP)	5144-01-01
Isolated Input Board (ECG/RESP & 2Temps)	5144-02-01
Isolated Input Board (ECG/RESP & 2Press)	5144-03-01
$EtCO_2$ Interface Board	5108-00-01

Modules and Assemblies

Part	Ivy Part Number
Replacement Battery	110007
EOS Power Supply 60W	580025
Masimo Sp02 Module (MS-3)	580022
Colin M2000 NIBP Module	580024
$EtCO_2$ Signal Processor Board	580011
$EtCO_2$ Power Board	580012
LSI Telemetry Transmitter Module Kit	580016
Ethernet Module	580026
Color Display	570013
Recorder	380004
Rubber Feet	680010
Pneumatic Hose for NIBP	560000
Window	2457-00-13
Speaker Assembly	2616-00-10
Fan Assembly	2620-00-10
Rear Enclosure (Rear bezel)	2566-00-11
Front Bezel	2565-00-11
Handle	2570-00-11

Fuses

CAUTION: To ensure safety and reliability, always replace fuses with the type specified.

Part	Description	Ivy Part Number
Power Entry Module (2)	1.6ASB, 5x20mm	290021
Mother Board – F1	5ASB, ASSY, SMT.	290503
Mother Board – F2, F3 & F4	3/8ASB, ASSY, SMT	290502

Cables and Harnesses

Part	Ivy Part Number
Masimo Internal $Sp0_2$ Cable	2451-01-01
Andros Internal $EtCO_2$ Cable	2317-01-01
$EtCO_2$ Signal Power Supply Harness Assembly	2335-00-01
$EtCO_2$ Signal Interface Harness Assembly	2336-00-01
Backlight Inverter	2470-01-10
NIBP Interface Ribbon	2609-00-10
Recorder Interface Ribbon	2608-00-10
COM 1 & COM 2 Interface Ribbon	2614-00-10
Telemetry Interface Ribbon	2611-00-10
Power Supply Input	2612-00-01
Power Entry Module	2613-00-01
Display Interface Ribbon	2615-00-10
Analog Output Interface Ribbon	2619-00-10
Horizontal Front Panel	2605-00-10
Vertical Front Panel	2577-00-10
Harness Interface Ribbon	2466-00-10

Labels

Part	Ivy Part Number
Front Panel Label, Vertical	2458-00-10
Front Panel Label, Horizontal	2596-00-10
Ivy Model Number Label (Masimo)	2599-01-10
Rear Panel Label	2598-00-10
Input Connector Label (ECG/Resp, NIBP, Sp02, 2Temp, 2Press, $EtCO_2$)	2597-01-10
Input Connector Label (ECG/Resp, NIBP, Sp02, 2Temp, 2Press)	2597-03-10
Input Connector Label (ECG/Resp, NIBP, Sp02 , 2Temp)	2597-05-10
Input Connector Label (ECG/Resp, NIBP, Sp02 , 2 Press)	2597-07-10
Input Connector Label (ECG/Resp, NIBP, Sp02)	2597-09-10

Software

Part	Description	Ivy Part Number
Mother Board – U57	450C Program (1 of 2)	2600-00-04
Mother Board – U53	450C Program (2 of 2)	2601-00-04
Mother Board – U26	DSP software	2636-00-04
Mother Board – U98	450C Video	2634-00-04

DISASSEMBLY AND ASSEMBLY

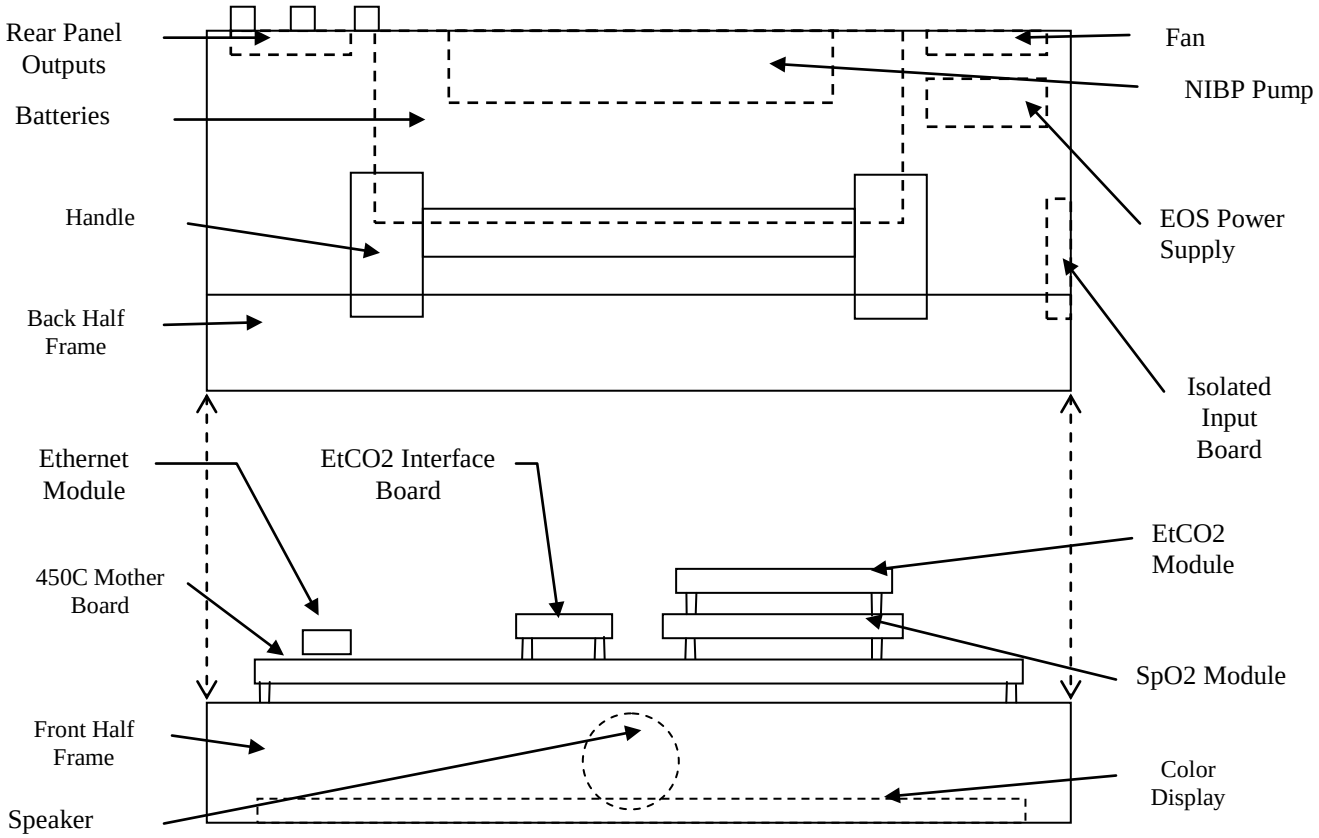
Covers

WARNING: To prevent equipment damage and possible personal injury, always remove the power cord from the instrument.

1. Remove the four screws that secure the back half frame to the front half frame (front bezel).

2. Carefully unplug the following harnesses from the 450C mother board: Power harness, ground connector, COM1 & COM2 harness, ECGX1000, ANALOG OUTPUT harness, NIBP harness, Recorder harness, SpO2 Connector, EtCO2 connector (if available) and Ethernet connector (if available).

The monitor should be open in two, the front half and the back half. Attached to the front half is the Mother board (5143-00-01), the color display and both horizontal and vertical faceplates. The back half contains the batteries, NIBP pump, Analog and digital outputs, the EOS power supply and the isolated input board (5144-00-01).



Printed Circuit Boards

450C Mother (5143) Board

1. Open the monitor as describe in the previous section.

2. Take the front half of the monitor and remove the three screws (located at each corner of the 5143 board) that hold the board to the front half.

3. Disconnect the front panel interface ribbon cable and the speaker harness.

$EtCO_2$ Module Interface (5108) Board

The EtCO2 module interface board is mounted on the Mother board next to the SpO2 module and the EtCO2 module.

1. Open the monitor as described above.

2. Disconnect the EtCO2 signal interface harness and EtCO2 power supply harness from J204 and J202 on the EtCO2 mother interface board.

3. Remove the three nylon screws that hold the EtCO2 interface board and carefully pull it up to release it from the Mother board.

$EtCO_2$ Module

The EtCO2 module is mounted on the Mother board next to the SpO2 module.

1. Open the monitor as described above.

2. Disconnect the EtCO2 signal interface harness and EtCO2 power supply harness from J204 and J202 on the EtCO2 module.

3. Remove the three screws that hold the EtCO2 module to the Motherboard.

Masimo SpO_2 Module

The Masimo module is attached to the 5143 board (the module is approximately at the middle of the 5143 board).

1. Open the monitor as described above.

2. Unplug the ribbon cable from the Masimo module.

3. Remove the three nylon screws that secure the module.

Isolated Input Board

NOTE: The screws securing the side panel to the monitor are covered by an adhesive label with the identification for the connectors on the panel. To gain access to the screws, you should carefully lift the label to expose the screws. If the label is damaged, it can be replaced by ordering Ivy P/N 2597-01-10.

1. Remove the four screws that secure the front half (front bezel) and back half of the monitor and unplug all the ribbon cables and harnesses from the 450C motherboard.

2. Remove the nuts from the outside of the temperature jacks (if present) and peel the adhesive label.

3. Unscrew the EtCO2 input connector (if present) and remove it from the monitor's frame.

4. Remove the four screws that secure the isolated input board to the monitor's frame.

5. Remove the two screws that hold the SpO_2 input cable and pull it out from the monitor's frame.

Front Panel

Use the following procedure to replace the horizontal front panel assembly.

1. Remove the four screws that secure the front half (front bezel) and back half of the monitor and unplug all the ribbon cables from the 450C motherboard.

2. Take out the three screws that secure the motherboard to the front half and carefully remove the board.

3. Carefully disconnect the 18 pin Interface ribbon cable and the speaker harness from the motherboard.

4. Disconnect the 10-pin ribbon cable that connects the vertical and horizontal faceplates.

5. Remove the four hex nut that hold the horizontal front panel to the front bezel (front half).

6. Pull the horizontal front panel out.

CAUTION: Do not bend any pins when removing the front panel connector from the Mother Board. Bent pins might require replacement of the Mother Board.

Use the following procedure to replace the vertical front panel assembly.

1. Remove the four screws that secure the front half (front bezel) and back half of the monitor and unplug all the ribbon cables from the 450C motherboard.

2. Take out the three screws that secure the motherboard to the front half and carefully remove the board.

3. Carefully disconnect the 18 pin Interface ribbon cable and the speaker harness from the motherboard.

4. Disconnect the 10-pin ribbon cable that connects the vertical and horizontal faceplates.

5. Remove the two hex nut that hold the vertical front panel to the front bezel (front half).

6. Pull the vertical front panel out.

CAUTION: Do not bend any pins when removing the front panel connector from the Mother Board. Bent pins might require replacement of the Mother Board.

EOS Power Supply

1. Open the monitor as described above.
2. Remove the Isolated Input Board.
3. Remove the four screws that secure the EOS Power Supply to the monitor's back frame.
4. Disconnect the connectors from the EOS Power Supply, including the ground wire connector.

Recorder Assembly

1. Open the recorder door and remove the paper from the recorder.
2. Loosen the two captive Philips-head screws inside the recorder housing.
3. Pull the Recorder Assembly straight out from the monitor.

NIBP Module

The NIBP module is mounted in the back half frame of the unit under the NIBP mounting bracket.

1. Remove the four screws that secure the front half (front bezel) and back half of the monitor and unplug all the ribbon cables and harnesses from the 450C motherboard.
2. Remove the recorder (if present) as described above.
3. Remove the two hex-nut that hold the ground points over the NIBP mounting bracket and remove all ground wires.
4. Remove the four screws (located to the sides of the bracket) that secure the NIBP mounting bracket to the back half frame and take the bracket out; the NIBP pump is attached to it.
5. Once the bracket is out, remove the four screws placed at each corner of the bracket and release the NIBP pump.

Battery Removal

The batteries are secure to the back half frame of the monitor by the Battery bracket. The Battery bracket has to be removed to replaced the batteries.

1. Remove the four screws that secure the front half (front bezel) and back half of the monitor and unplug all the ribbon cables and harnesses from the 450C motherboard.

2. Unplug the wires at the batteries terminals.

3. Remove the four screws that hold the battery bracket to the unit. Two screws are located on the rear panel and the other two are in the bottom of the back half frame.

4. Remove the battery bracket and the batteries.

Display Assembly

The Display Assembly is mounted on the front half frame under the motherboard. To remove the Display Assembly follows the next steps:

1. Remove the four screws that secure the front half (front bezel) and back half of the monitor and unplug all the ribbon cables from the 450C motherboard.

2. Remove the motherboard as described previously. Unplug the speaker harness and the front panel ribbon cable from the motherboard.

3. Remove the four screws that hold the display to the front half frame and lift the display up.

NOTE: When installing back the display, the screws must be tight at 60 lb/in

4. Remove the four screws that secure the Display Power Supply to the front bezel.

NOTE: The Display Assembly and Display Power Supply must be replaced as a pair.

Speaker

1. Open the monitor as described in the first section of this chapter.

2. Remove the Mother Board and unplug the speaker harness.

3. Pull the speaker out from its location.

BOARD LAYOUT DIAGRAMS

1. EtCO2 Interface Board	5108-00-02
2. 450C Monitor Mother Board (front)	5143-00-02
3. 450C Monitor Mother Board (back)	5143-00-02
4. Isolated Input Board (solder side)	5144-00-02
5. Isolated Input Board (connector side)	5144-00-02

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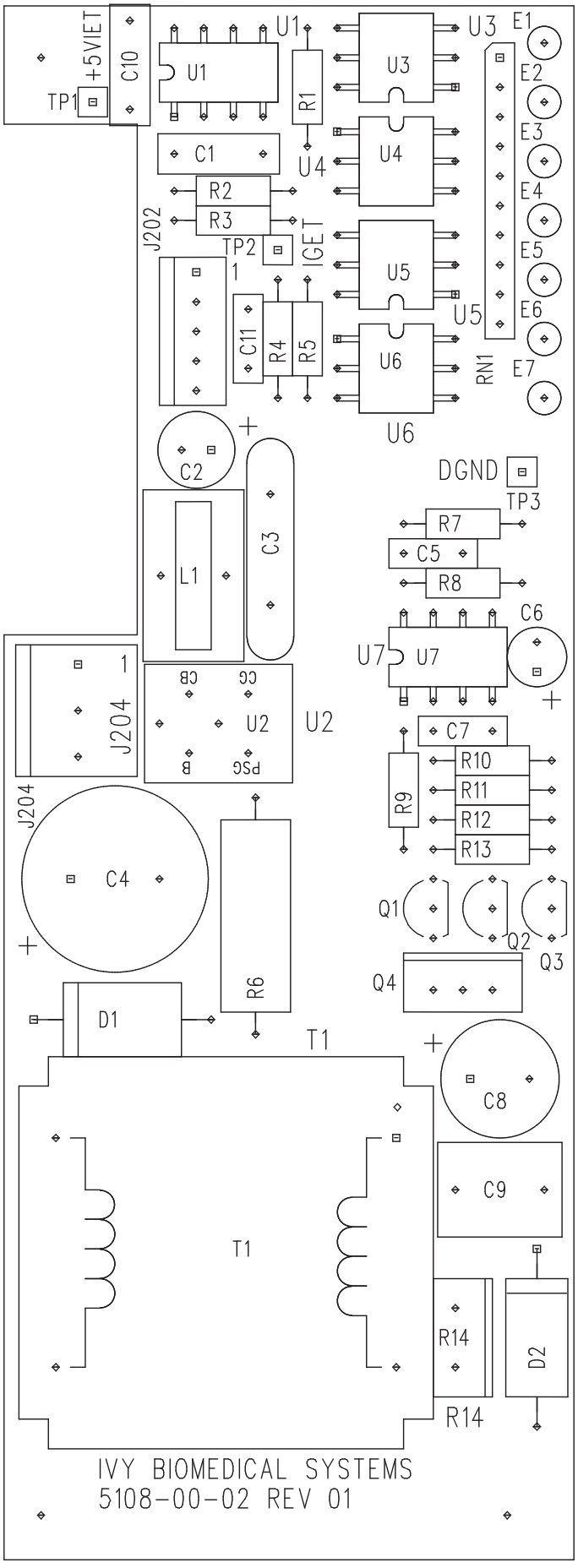
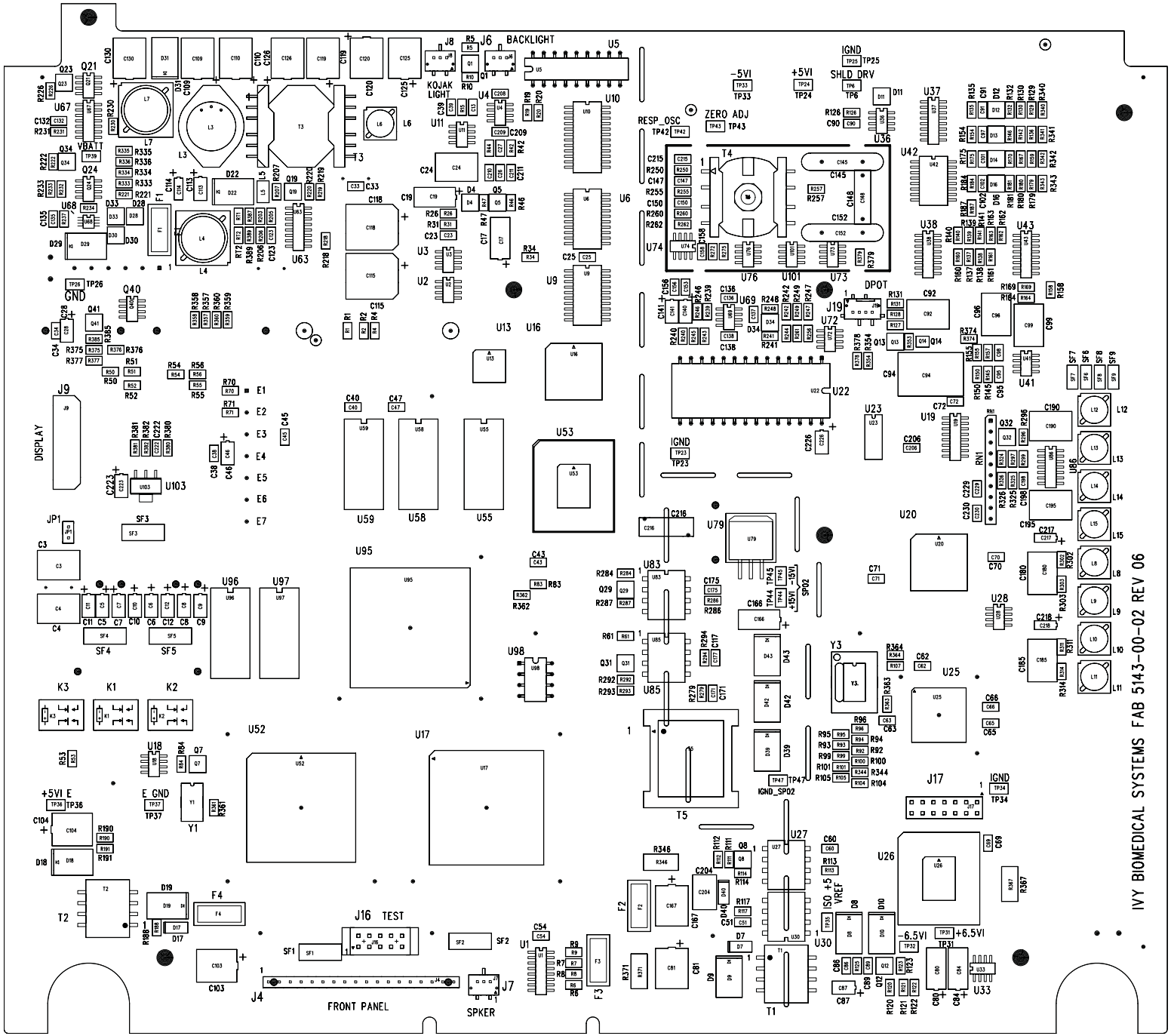
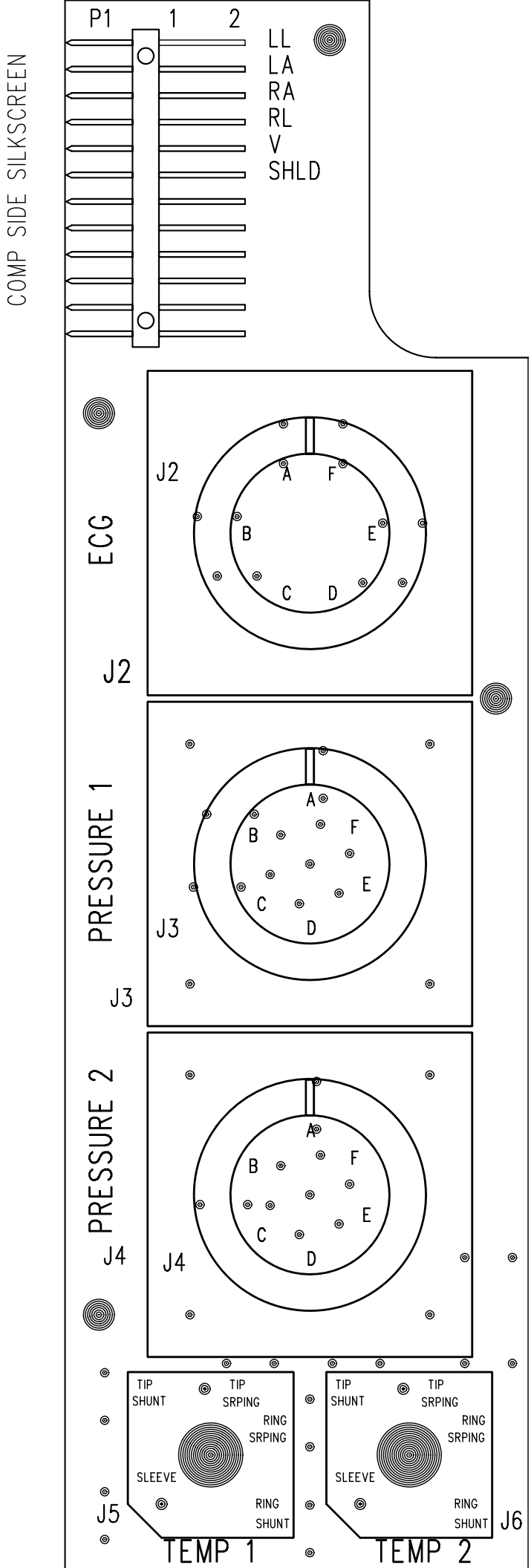


1 SILKSCREEN


BACKLIGHT
KOJAK LIGHT
VBATT
GND
DISPLAY
RESP_OSC
ZERO ADJ
-5VI
+5VI
SHLD DRV
IGND
DPOT
+5VI E
E GND
IGND_SPO2
ISO +5 VREF
-6.5VI
+6.5VI
J16 TEST
FRONT PANEL
SPKER
IVY BIOMEDICAL SYSTEMS FAB 5143-00-02 REV 06
1 SII KSCRFFN

IVY BIOMEDICAL SYSTEMS 450C MONITOR MOTHER BD ASSY 5143-[redacted]-01 REV [redacted] LOT NO: [redacted] SER NO: [redacted]
FAB 5143-00-02 REV 06
LAYER 6
ISOLATED INPUTS
J5
ECGX1000
PRESS TEST
PRESS 1
PRESS 2
TEMP 1
TEMP 2
RESET_DSP
BASE IMP
ANNALOG IN
RESP LOW
RESP HI
SpO2
+5VI SPO2
IGND_SPO2
AGND
DGND
-12V
+5V REF
+12V
SPEAKER
FAN
BC_TMR
VCC_BC
GND_REC
THERMISTOR
VCC
BATT+
BATT-
GND
EOS_OUT
J2 POWER
J20 CGND
RECORDER
J3
J12
BWI
NIBP
J1
J14
J10 COM1
J11 COM2
J24
J13 ANALOG OUT
RESET
ETHERNET
J15
IGND


COMP SIDE SILKSCREEN
P1
1
2
LL
LA
RA
RL
V
SHLD
ECG
J2
A
F
B
E
C
D
J2
PRESSURE 1
J3
A
B
F
E
C
D
J3
PRESSURE 2
J4
A
B
F
E
C
D
J4
TIP
SHUNT
TIP
SRPING
RING
SRPING
SLEEVE
RING
SHUNT
J5
TEMP 1
TIP
SHUNT
TIP
SRPING
RING
SRPING
SLEEVE
RING
SHUNT
J6
TEMP 2

SOLDER SIDE SILKSCREEN 5144-00-05 REV 01 ISOLATED INPUT MODEL 4305 IVY BIOMEDICAL SYSTEMS DRW NO: IVY5298

SCHEMATIC DIAGRAMS

1. EtCO2 Module Interface Board 5108-00-01

2. 450C Monitor Mother Board 5143-00-01
   a. 5143 Main (1 of 16)
   b. Analog (2 of 16)
   c. Bypass (3 of 16)
   d. COMM (4 of 16)
   e. Color CPU Main (5 of 16)
   f. DSP Processor (6 of 16)
   g. DSP Power Supply (7 of 16)
   h. ECG Front End (8 of 16)
   i. Ethernet Power Supply (9 of 16)
   j. Glue (10 of 16)
   k. CPU Memory (11 of 16)
   l. Power Supply (12 of 16)
   m. Resp (13 of 16)
   n. SpO2 Power Supply (14 of 16)
   o. Temp Pressure Front End (15 of 16)
   p. Video FPGA (16 of 16)

3. Isolated input board 5144-00-01

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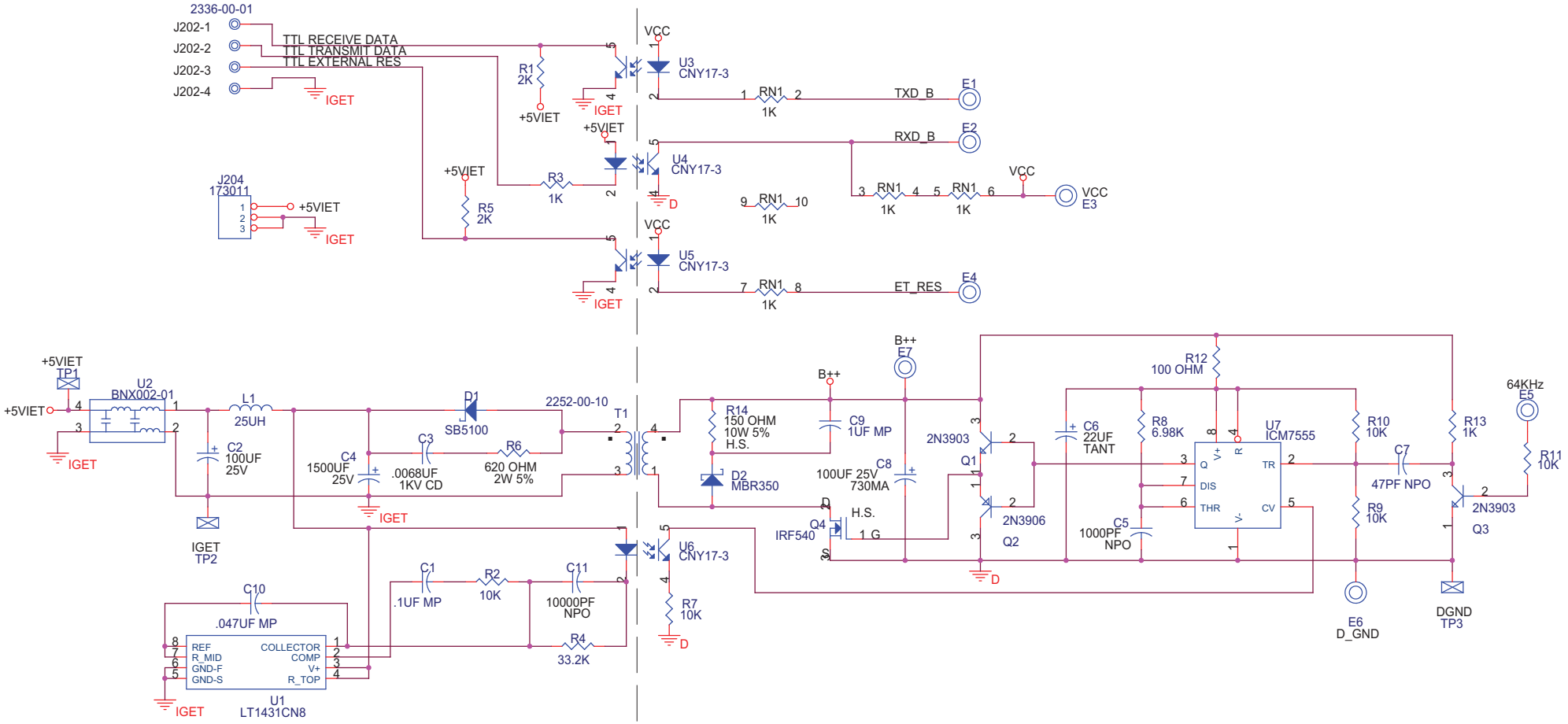
REVISIONS			
REV	DESCRIPTION	BY	DATE
01	REVISED PER ECN 691.	GP	8-28-97
02	REVISED PER ECN 709.	GP	11-4-97
03	REVISED PER ECN 957.	GP	6-25-99
04	REVISED PER ECN 1201.	GP	8-9-02

ISOLATED

NON-ISOLATED



NOTES:

1. ALL RESISTORS ARE 1/4W, 1% U.O.S.
2. LAST USED:
3. NOT USED:

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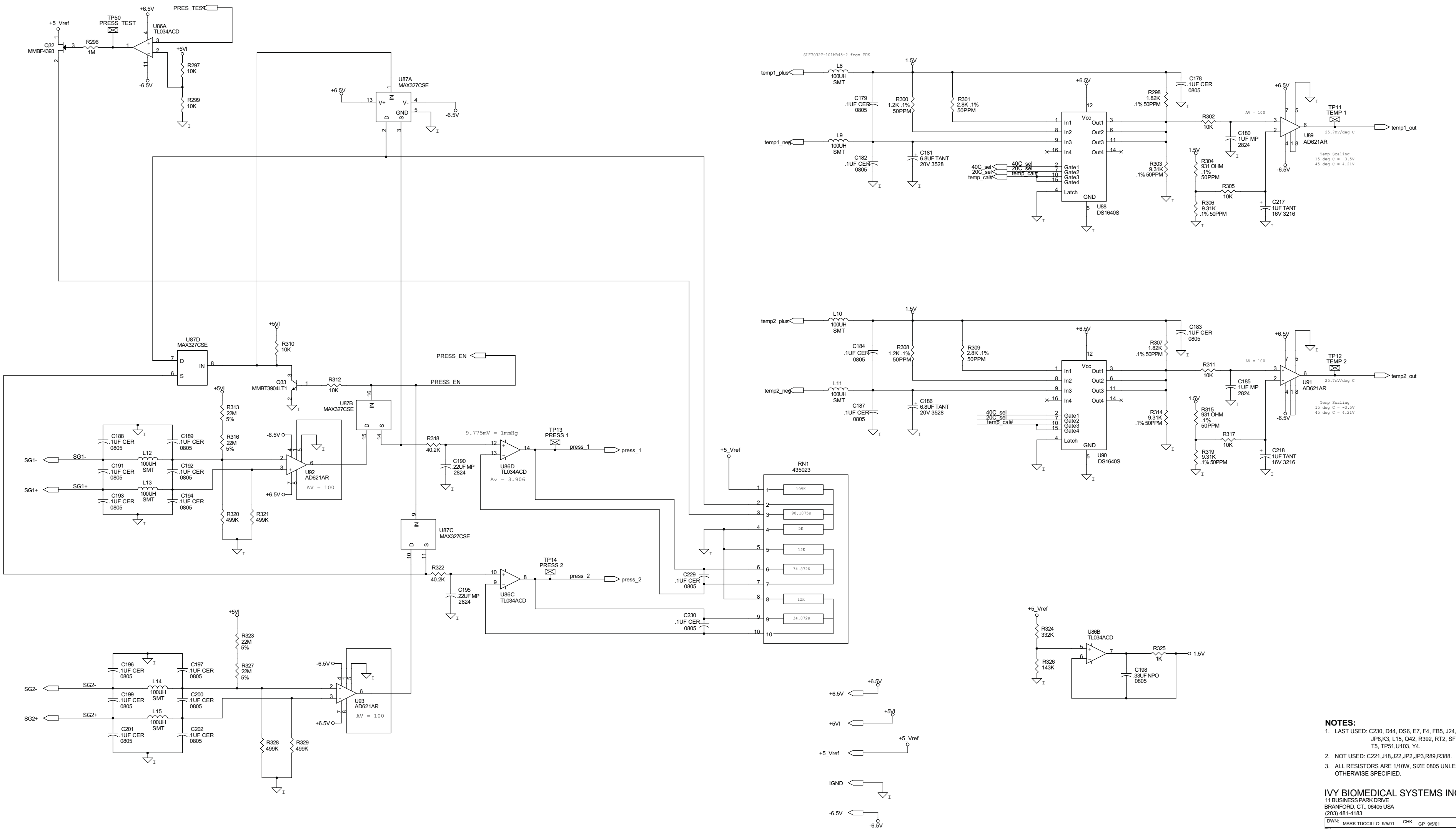
Title	ETCO2 MODULE INTERFACE BOARD ASSEMBLY
Size	B
Document Number	5108-00-01 (-03 SCHEMATIC)
Rev	04
Date:	Thursday, March 10, 2005
Sheet	1 of 1

REVISIONS

REV	DESCRIPTION	BY	DATE
	FOR REVISION LEVEL HISTORY REV-00 THRU REV-17 REFER TO ECN 1274 IN THE ENGINEERING RECORD FILES.		
18	REVISED PER ECN 1274.	GP	6-11-03
19	REVISED PER ECN 1275.	GP	6-11-03
20	REVISED PER ECN 1289.	GP	6-25-03
21	REVISED PER ECN 1290.	GP	6-25-03
22	REVISED PER ECN 1326.	GP	3-4-04
23	REVISED PER ECN 1354.	GP	4-13-04
24	REVISED PER ECN 1432.	GP	5-27-05



NOTES:

1. LAST USED: C230, D44, DS6, E7, F4, FB5, J24, JP8,K3, L15, Q42, R392, RT2, SF11, T5, TP51,U103, Y4.
2. NOT USED: C221,J18,J22,JP2,JP3,R89,R388.
3. ALL RESISTORS ARE 1/10W, SIZE 0805 UNLESS OTHERWISE SPECIFIED.

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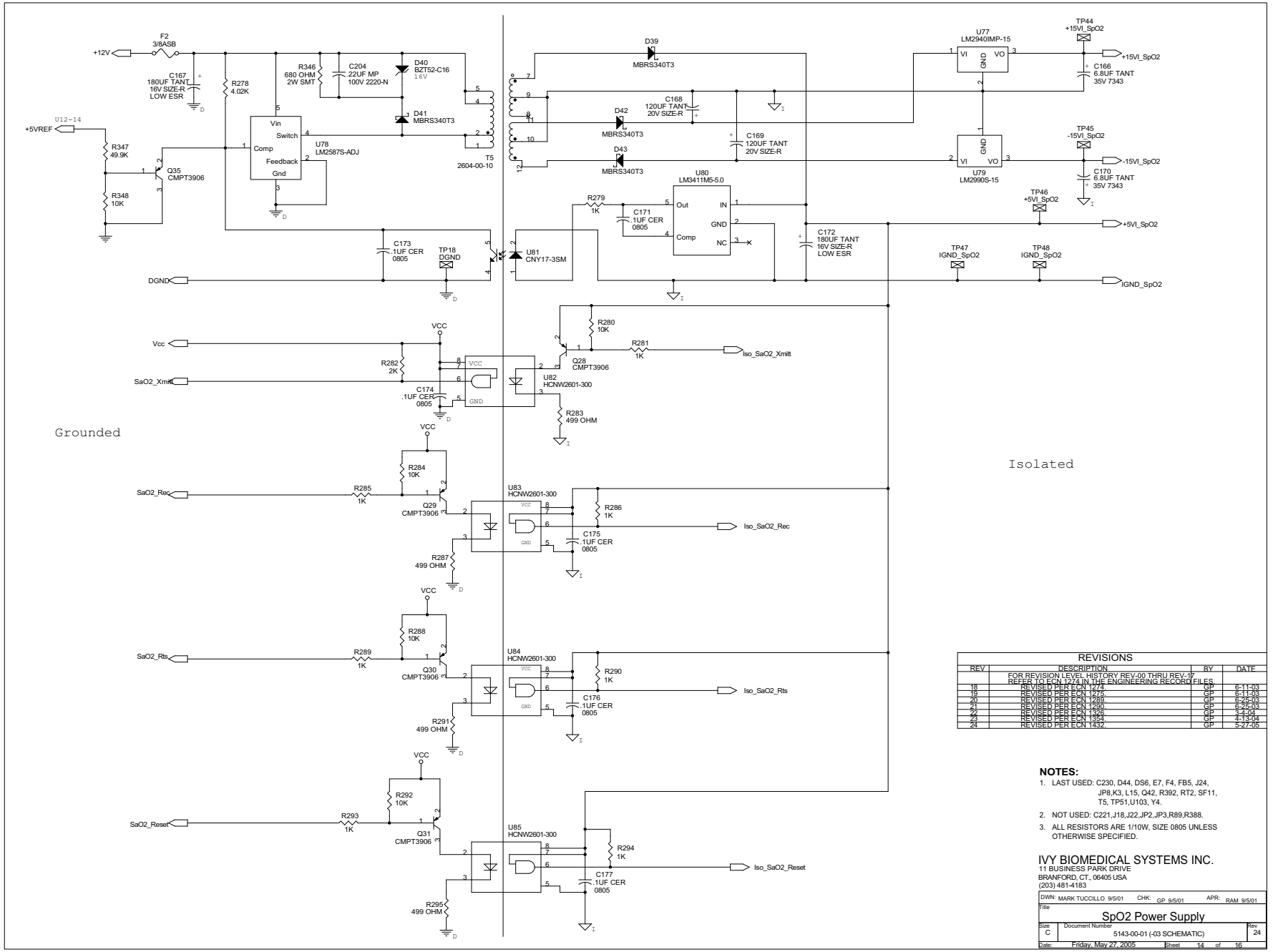
DWN: MARK TUCCILLO 9/5/01	CHK: GP 9/5/01	APR: RAM 9/5/01
Title: Temp Pressure Front End		
Size: D	Document Number: 5143-00-01 (-03 SCHEMATIC)	Rev: 24
Date: Friday, May 27, 2005	Sheet 15 of 16	



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REV	DESCRIPTION	BY	DATE
	FOR REVISION LEVEL HISTORY REV-00 THRU REV-17 REFER TO ECN 1274 IN THE ENGINEERING RECORD FILES.		
18	REVISED PER ECN 1274.	GP	6-11-03
19	REVISED PER ECN 1275.	GP	6-11-03
20	REVISED PER ECN 1288.	GP	6-25-03
21	REVISED PER ECN 1290.	GP	6-25-03
22	REVISED PER ECN 1328.	GP	3-4-04
23	REVISED PER ECN 1354.	GP	4-13-04
24	REVISED PER ECN 1432.	GP	5-27-05

NOTES:

1. LAST USED: C230, D44, DS6, E7, F4, FB5, J24, JP8,K3, L15, Q42, R392, RT2, SF11, T5, TP51,U103, Y4.
2. NOT USED: C221,J18,J22,JP2,JP3,R89,R388.
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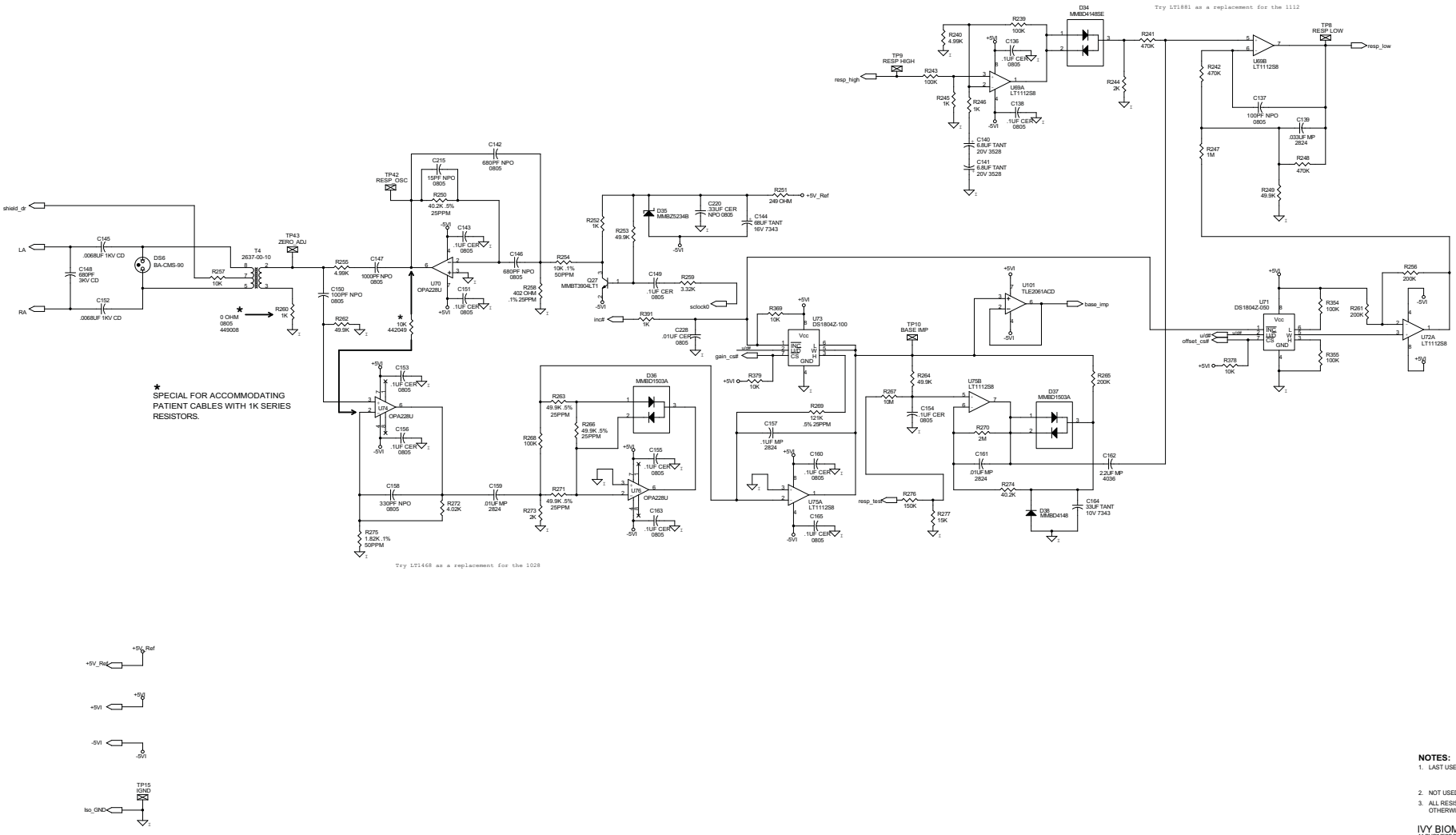
DWN: MARK TUCCILLO 9/5/01 CHK: GP 9/5/01 APR: RAM 9/5/01

Title: SpO2 Power Supply

Size: C | Document Number: 5143-00-01 (-03 SCHEMATIC) | Rev: 24

Date: Friday, May 27, 2005 | Sheet 14 of 16

REVISIONS			
REV	DESCRIPTION FOR REVISION LEVEL HISTORY REV.00 THRU REV.17 REFER TO ENTEVEN TOWN ENGINEERING RECORD FILES.	BY	DATE
18	REVISED PER ECN 1275	GP	6-11-03
19	REVISED PER ECN 1275	GP	6-11-03
20	REVISED PER ECN 1280	GP	6-25-03
21	REVISED PER ECN 1290	GP	6-25-03
22	REVISED PER ECN 1305	GP	3-4-04
23	REVISED PER ECN 1354	GP	4-19-04
24	REVISED PER ECN 1432	GP	5-27-05



NOTES:

1. LAST USED: C230, D44, DS6, E7, F4, FB5, J24, JP8,K3, L15, Q42, R392, RT2, SF11, T5, TP51,U103, Y4.
2. NOT USED: C221,J18,J22,JP2,JP3,R89,R388.
3. ALL RESISTORS ARE 1/10W, SIZE 0805 UNLESS OTHERWISE SPECIFIED.

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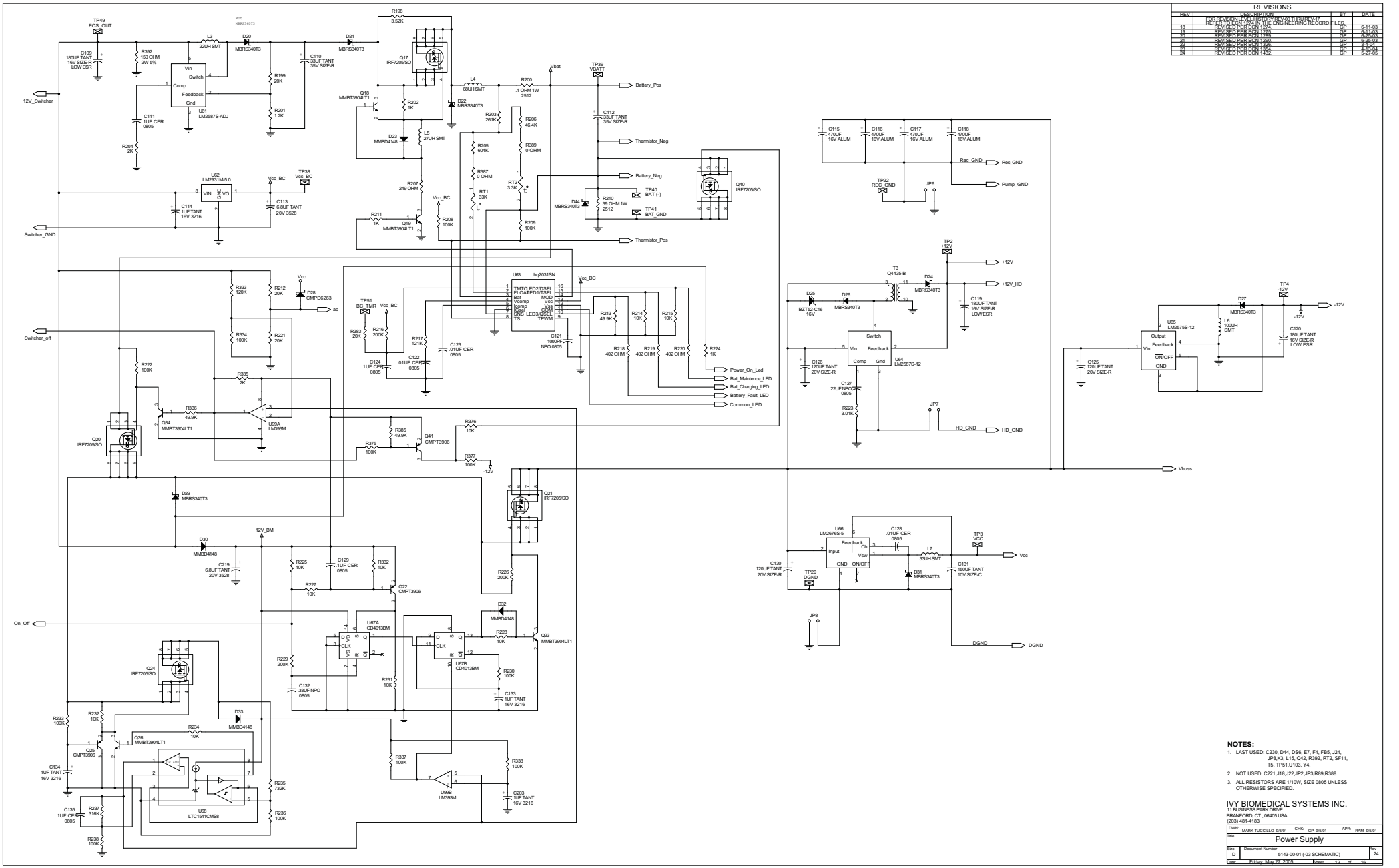
DWN	CHK	APR
MARK TUCCILLO 9/5/01	GP 9/5/01	RAM 9/5/01

Title: Resp

Size	Document Number	Rev
D	5143-00-01 (-03 SCHEMATIC)	24

Date: Friday, May 27, 2005 Sheet 13 of 16


REVISIONS
REV | DESCRIPTION | BY | DATE
FOR REVISION LEVEL HISTORY REV.00 THRU REV.17 REFER TO ENGINEERING RECORD FILES
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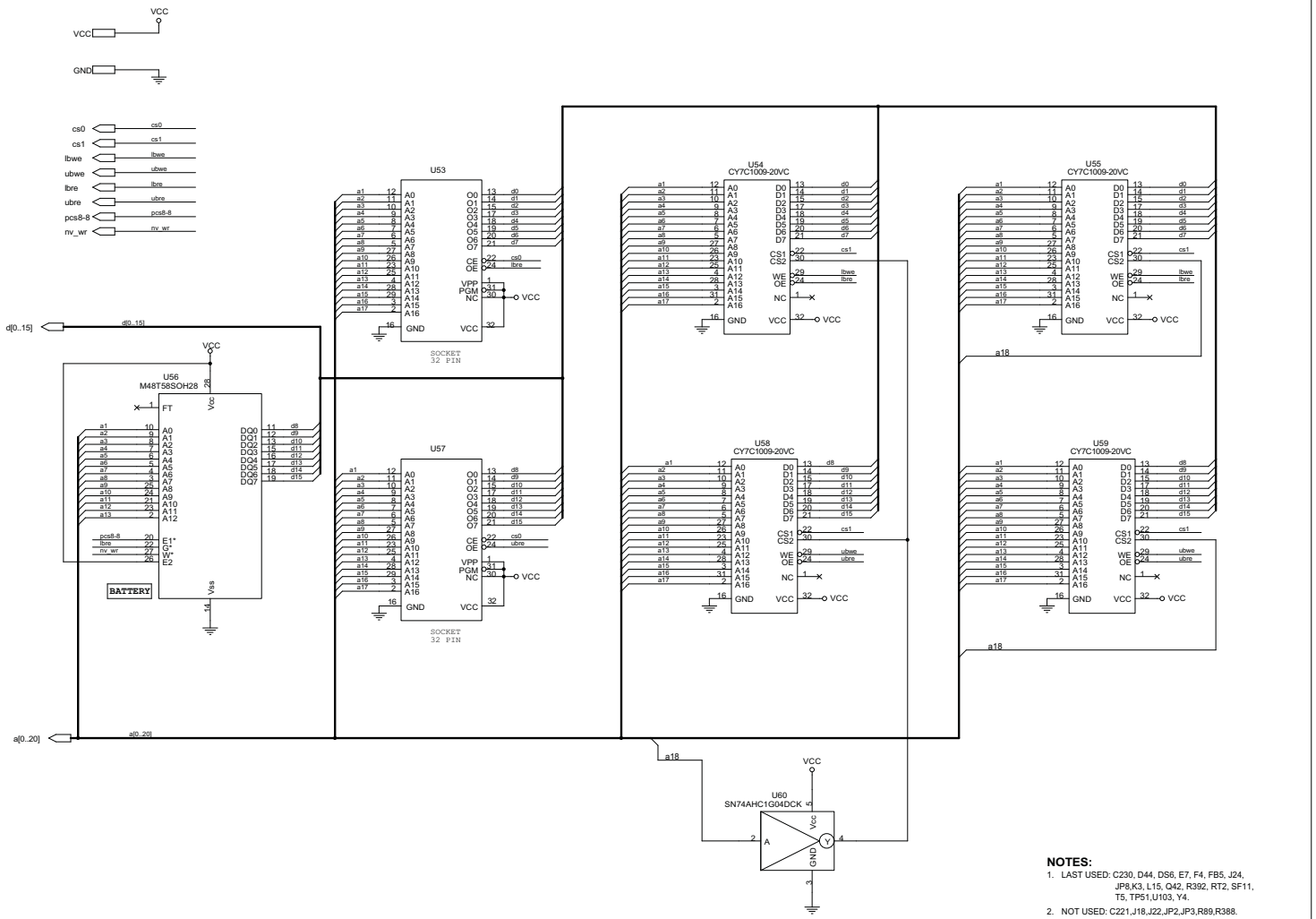
19 REVISED PER ECN 1275 GP 6-11-03
20 REVISED PER ECN 1280 GP 6-25-03
21 REVISED PER ECN 1290 GP 6-25-03
22 REVISED PER ECN 1305 GP 3-4-04
23 REVISED PER ECN 1354 GP 4-19-04
24 REVISED PER ECN 1432 GP 5-27-05
NOTES:
1. LAST USED: C230, D44, DS6, E7, F4, FB5, J24, JP8,K3, L15, Q42, R392, RT2, SF11, T5, TP51,U103, Y4.
2. NOT USED: C221,J18,J22,JP2,JP3,R89,R388.
3. ALL RESISTORS ARE 1/10W, SIZE 0805 UNLESS OTHERWISE SPECIFIED.
IVY BIOMEDICAL SYSTEMS INC.
11 BUSINESS PARK DRIVE
BRANFORD, CT., 06405 USA
(203) 481-4183
DWN: MARK TUCCILLO 9/5/01 CHK: GP 9/5/01 APP: RAM 9/5/01
Title: Power Supply
Size: D Document Number: 5143-00-01 (-03 SCHEMATIC) Rev: 24
Date: Friday, May 27, 2005 Sheet 12 of 16
TP49 EOS_OUT
C109 180UF TANT 16V SIZE-R LOW ESR
R392 150 OHM 2W 5%
L3 22UH SMT
D20 MBRS340T3
D21 MBRS340T3
C110 33UF TANT 35V SIZE-R
U61 LM2587S-ADJ
Vin Switch Comp Feedback Gnd
R199 20K
R201 1.2K
C111 1UF CER 0805
R204 2K
12V_Switcher
Switcher_GND
R198 3.52K
Q17 IRF7205/SO
Q18 MMBT3904LT1
R202 1K
D22 MBRS340T3
L4 68UH SMT
R200 .1 OHM 1W 2512
Vbat
TP39 VBATT
Battery_Pos
C112 33UF TANT 35V SIZE-R
Thermistor_Neg
Battery_Neg
TP40 BAT (-)
TP41 BAT_GND
Thermistor_Pos
D23 MMBD4148
L5 27UH SMT
R203 261K
R206 46.4K
R205 604K
R389 0 OHM
R387 0 OHM
RT2 3.3K
RT1 33K
R207 249 OHM
R209 100K
R208 100K
R211 1K
Q19 MMBT3904LT1
D44 MBRS340T3
R210 .39 OHM 1W 2512
Q40 IRF7205/SO
U62 LM2931M-5.0
VIN VO GND
C114 1UF TANT 16V 3216
C113 6.8UF TANT 20V 3528
TP38 Vcc_BC
Vcc_BC
C115 470UF 16V ALUM
C116 470UF 16V ALUM
C117 470UF 16V ALUM
C118 470UF 16V ALUM
Rec_GND
Pump_GND
TP22 REC_GND
JP6
U63 bq2031SN
TMT/LED2/DSEL FLOAT/LED1/TSEL Bat Vcomp Icomp IDset SNS LED3/CSEL TS
MOD Vcc Vss COM LED3/CSEL TPWM
C121 1000PF NPO 0805
R213 49.9K
R214 10K
R215 10K
R218 402 OHM
R219 402 OHM
R220 402 OHM
R224 1K
Power_On_Led
Bat_Maintence_LED
Bat_Charging_LED
Battery_Fault_LED
Common_LED
TP51 BC_TMR
R216 200K
R217 121K
R383 20K
C123 .01UF CER 0805
C122 .01UF CER 0805
C124 .1UF CER 0805
R333 120K
R212 20K
R334 100K
R221 20K
D28 CMPD6263
Vcc
ac
Switcher_off
R222 100K
R335 2K
Q20 IRF7205/SO
R336 49.9K
Q34 MMBT3904LT1
U99A LM393M
R385 49.9K
Q41 CMPT3906
R376 10K
R375 100K
R377 100K
-12V
D29 MBRS340T3
Q21 IRF7205/SO
12V_BM
D30 MMBD4148
C219 6.8UF TANT 20V 3528
R225 10K
C129 .1UF CER 0805
R332 10K
R227 10K
Q22 CMPT3906
R226 200K
On_Off
U67A CD4013BM
U67B CD4013BM
D32 MMBD4148
R228 10K
Q23 MMBT3904LT1
R229 200K
C132 33UF NPO 0805
R231 10K
R230 100K
C133 1UF TANT 16V 3216
Q24 IRF7205/SO
R233 100K
R232 10K
D33 MMBD4148
R234 10K
Q26 MMBT3904LT1
Q25 CMPT3906
C134 1UF TANT 16V 3216
R337 100K
R338 100K
U99B LM393M
C203 1UF TANT 16V 3216
R235 732K
R236 100K
U68 LTC1541CMS8
C135 .1UF CER 0805
R237 316K
R238 100K
T3 Q4435-B
D24 MBRS340T3
D25 BZT52-C16 16V
D26 MBRS340T3
+12V
+12V_HD
C119 180UF TANT 16V SIZE-R LOW ESR
U64 LM2587S-12
Switch Vin Feedback Comp Gnd
C126 120UF TANT 20V SIZE-R
C127 .22UF NPO 0805
R223 3.01K
JP7
HD_GND
TP4 +12V
D27 MBRS340T3
L6 100UH SMT
C120 180UF TANT 16V SIZE-R LOW ESR
U65 LM2575S-12
Output Feedback Vin ON/OFF GND
C125 120UF TANT 20V SIZE-R
Vbuss
U66 LM2676S-5
Feedback Input Cb Vsw GND ON/OFF
C128 .01UF CER 0805
L7 33UH SMT
C130 120UF TANT 20V SIZE-R
C131 150UF TANT 10V SIZE-C
TP3 VCC
TP20 DGND
D31 MBRS340T3
JP8
DGND

REVISIONS			
REV	DESCRIPTION FOR REVISION LEVEL HISTORY REV-00 THRU REV-17 REFER TO ECN 1274 IN THE ENGINEERING RECORD FILES.	BY	DATE
18	REVISED PER ECN 1274	GP	6-11-03
19	REVISED PER ECN 1275	GP	6-11-03
20	REVISED PER ECN 1289	GP	6-25-03
21	REVISED PER ECN 1290	GP	6-25-03
22	REVISED PER ECN 1326	GP	3-4-04
23	REVISED PER ECN 1351	GP	4-13-04
24	REVISED PER ECN 1432	GP	5-27-05



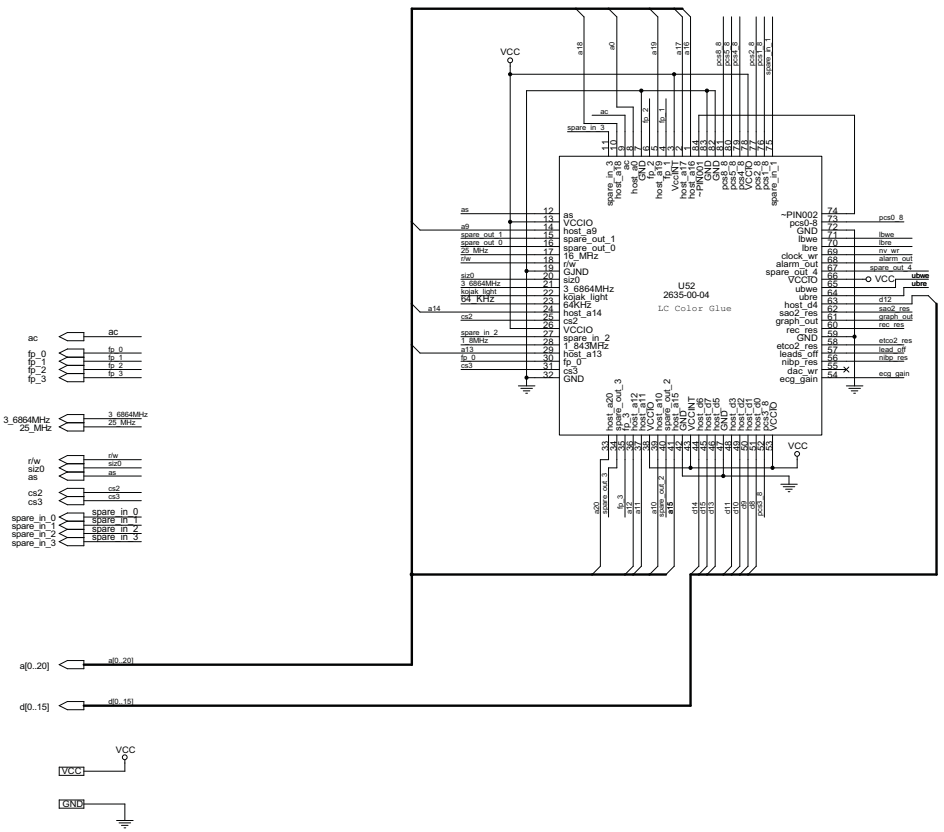
NOTES:

1. LAST USED: C230, D44, DS6, E7, F4, FB5, J24, JP8,K3, L15, Q42, R392, RT2, SF11, T5, TP51,U103, Y4.
2. NOT USED: C221,J18,J22,JP2,JP3,R89,R388.
3. ALL RESISTORS ARE 1/10W, SIZE 0805 UNLESS OTHERWISE SPECIFIED.

IVY BIOMEDICAL SYSTEMS INC.
11 BUSINESS PARK DRIVE
BRANFORD, CT., 06405 USA
(203) 481-4183

DWN: MARK TUCCILLO 9/5/01	CHK: GP 9/5/01	APR: RAM 9/5/01	
Title: CPU Memory			
Size: C	Document Number: 5143-00-01 (-03 SCHEMATIC)		Rev: 24
Date: Friday, May 27, 2005	Sheet 11 of 16		

REVISIONS			
REV	DESCRIPTION FOR REVISION LEVEL HISTORY REV-00 THRU REV-17 REFER TO ECN 1274 IN THE ENGINEERING RECORD FILES.	BY	DATE
18	REVISED PER ECN 1274	GP	6-11-03
19	REVISED PER ECN 1275	GP	6-11-03
20	REVISED PER ECN 1289	GP	6-25-03
21	REVISED PER ECN 1290	GP	6-25-03
22	REVISED PER ECN 1326	GP	3-4-04
23	REVISED PER ECN 1353	GP	4-19-04
24	REVISED PER ECN 1432	GP	5-27-05

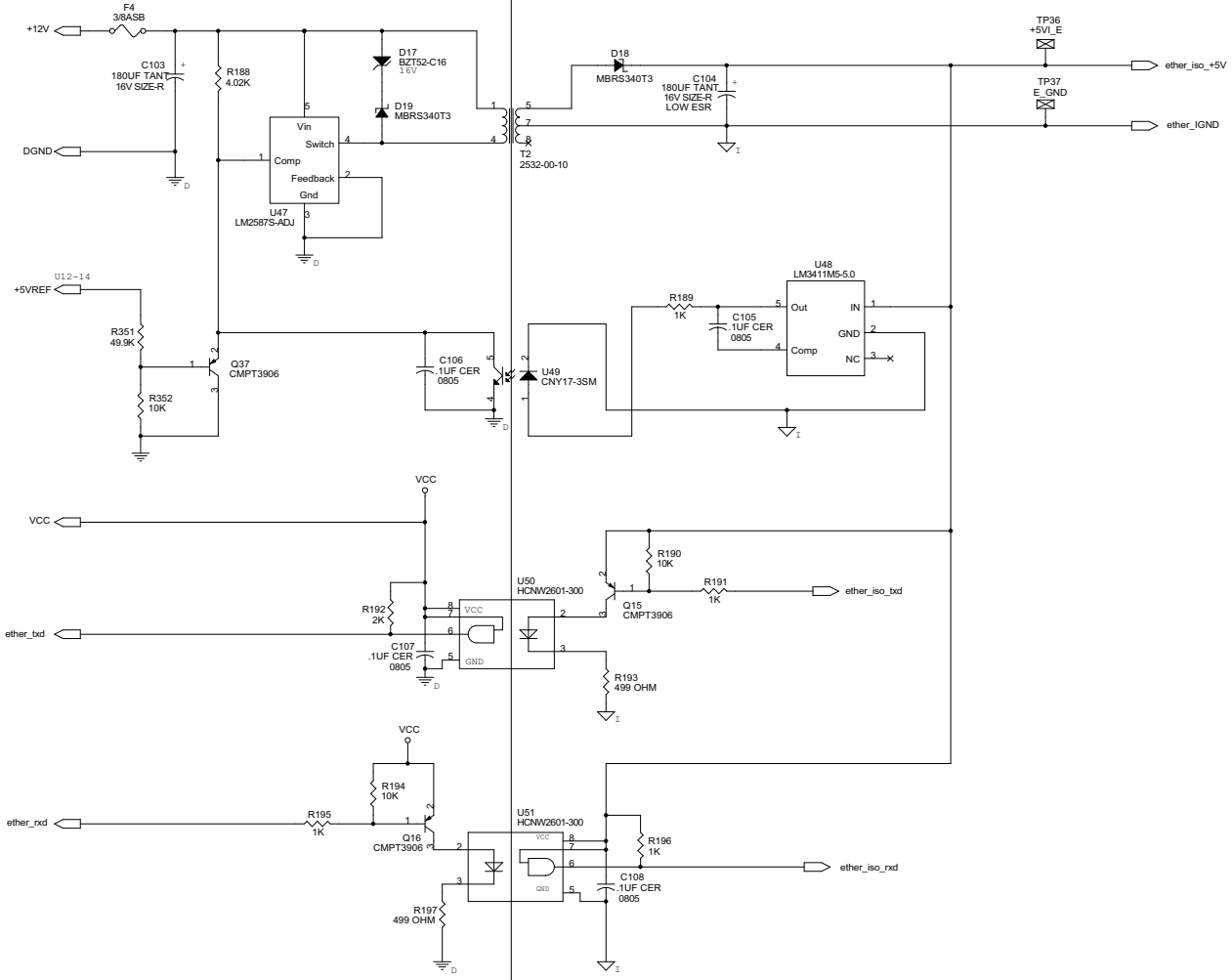


NOTES:

1. LAST USED: C230, D44, DS6, E7, F4, FB5, J24, JP8,K3, L15, Q42, R392, RT2, SF11, T5, TP51,U103, Y4.
2. NOT USED: C221,J18,J22,JP2,JP3,R89,R388.
3. ALL RESISTORS ARE 1/10W, SIZE 0805 UNLESS OTHERWISE SPECIFIED.

IVY BIOMEDICAL SYSTEMS INC.
11 BUSINESS PARK DRIVE
BRANFORD, CT., 06405 USA
(203) 481-4183

DWN: MARK TUCCILLO 9/5/01	CHK: GP 9/5/01	APR: RAM 9/5/01	
Title: GLUE			
Size: C	Document Number: 5143-00-01 (-03 SCHEMATIC)		Rev: 24
Date: Friday, May 27, 2005	Sheet 10 of 16		



REVISIONS			
REV	DESCRIPTION FOR REVISION LEVEL HISTORY REV-00 THRU REV-17 REFER TO ECN 1274 IN THE ENGINEERING RECORD FILES.	BY	DATE
18	REVISED PER ECN 1274	GP	6-11-03
19	REVISED PER ECN 1275	GP	6-11-03
20	REVISED PER ECN 1289	GP	6-25-03
21	REVISED PER ECN 1290	GP	6-25-03
22	REVISED PER ECN 1328	GP	3-4-04
23	REVISED PER ECN 1354	GP	4-13-04
24	REVISED PER ECN 1432	GP	5-27-05

OPTIONAL

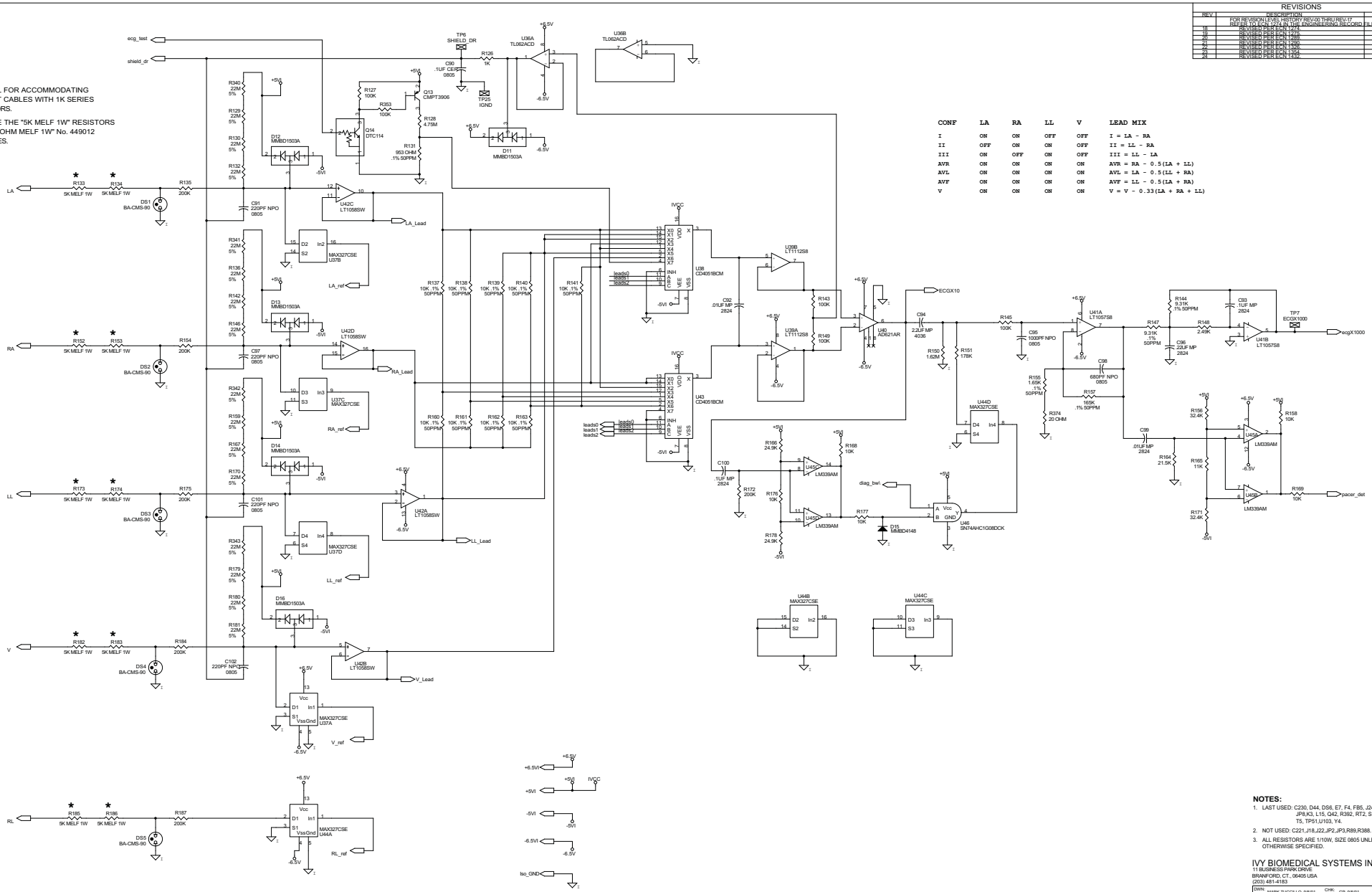
THIS CIRCUITRY IS FOR THE ETHERNET OPTION

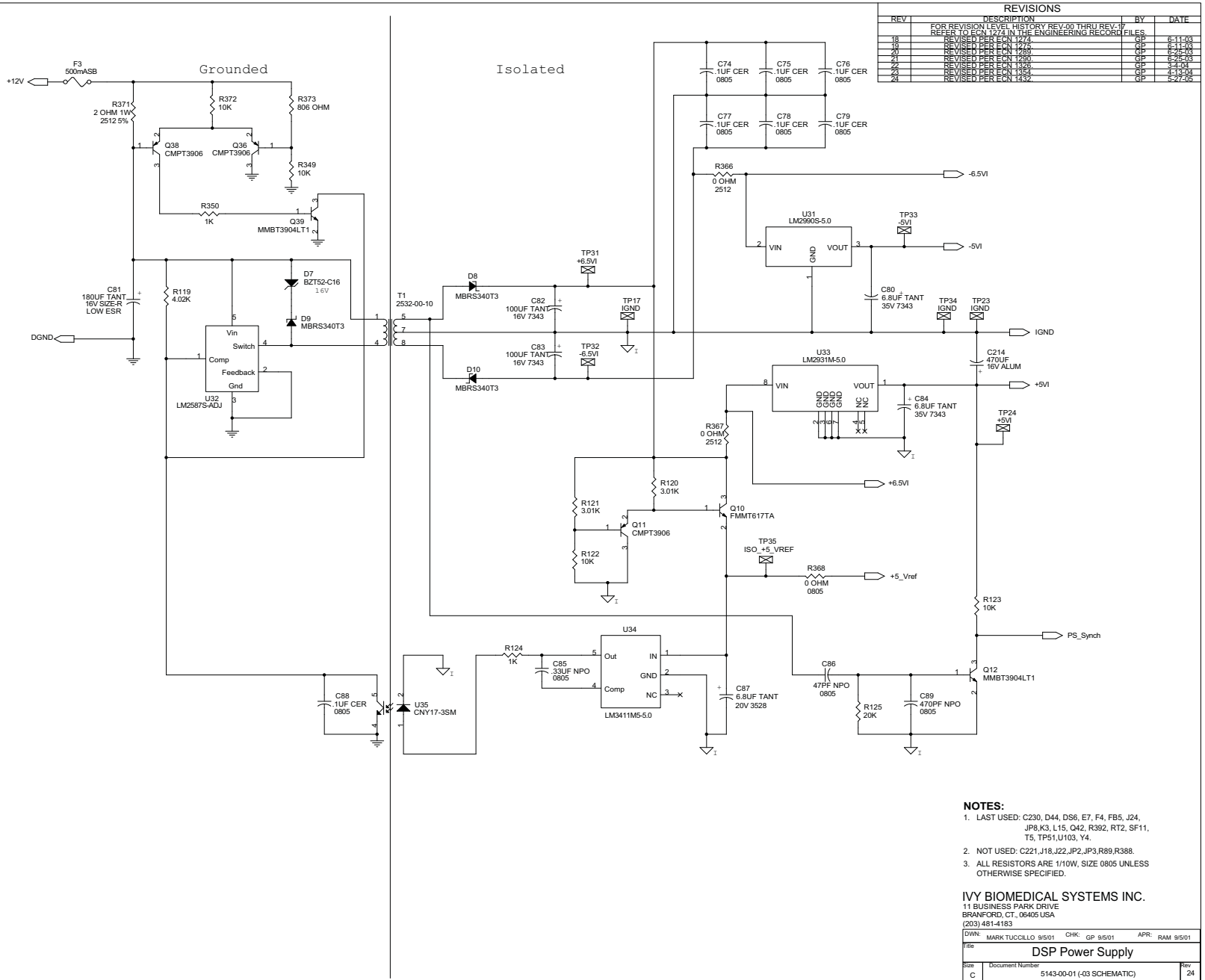
NOTES:

1. LAST USED: C230, D44, DS6, E7, F4, FB5, J24, JP8,K3, L15, Q42, R392, RT2, SF11, T5, TP51,U103, Y4.
2. NOT USED: C221,J18,J22,JP2,JP3,R89,R388.
3. ALL RESISTORS ARE 1/10W, SIZE 0805 UNLESS OTHERWISE SPECIFIED.

IVY BIOMEDICAL SYSTEMS INC.
11 BUSINESS PARK DRIVE
BRANFORD, CT., 06405 USA
(203) 481-4183

DWN: MARK TUCCILLO 9/5/01	CHK: GP 9/5/01	APR: RAM 9/5/01	
Title: Ethernet Power Supply			
Size: C	Document Number: 5143-00-01 (-03 SCHEMATIC)		Rev: 24
Date: Friday, May 27, 2005	Sheet 9 of 16		


REVISIONS
REV | DESCRIPTION | BY | DATE
FOR REVISION LEVEL HISTORY REV.00 THRU REV.17 REFER TO ENGINEERING RECORD FILES.
18 REVISED PER ECN 1275 GP 6-11-03
19 REVISED PER ECN 1276 GP 6-11-03
20 REVISED PER ECN 1289 GP 6-25-03
21 REVISED PER ECN 1290 GP 6-25-03
22 REVISED PER ECN 1305 GP 3-4-04
23 REVISED PER ECN 1354 GP 4-19-04
24 REVISED PER ECN 1492 GP 5-27-05
* SPECIAL FOR ACCOMMODATING PATIENT CABLES WITH 1K SERIES RESISTORS.
CHANGE THE "5K MELF 1W" RESISTORS TO "499 OHM MELF 1W" No. 449012 10 PLACES.
CONF LA RA LL V LEAD MIX
I ON ON OFF OFF I = LA - RA
II OFF ON ON OFF II = LL - RA
III ON OFF ON OFF III = LL - LA
AVR ON ON ON ON AVR = RA - 0.5(LA + LL)
AVL ON ON ON ON AVL = LA - 0.5(LL + RA)
AVF ON ON ON ON AVF = LL - 0.5(LA + RA)
V ON ON ON ON V = V - 0.33(LA + RA + LL)
ecg_test
shield_dr
TP6 SHIELD_DR
TP25 IGND
U36A TL062ACD
U36B TL062ACD
C90 .1UF CERAC 0805
R126 1K
Q13 CMPT3906
Q14 DTC114
R127 100K
R263 100K
R128 4.75M
R131 953 OHM .1% 50PPM
D11 MMBD1503A
D12 MMBD1503A
D13 MMBD1503A
D14 MMBD1503A
D16 MMBD1503A
LA
RA
LL
V
RL
R133 5K MELF 1W
R134 5K MELF 1W
R135 200K
R152 5K MELF 1W
R153 5K MELF 1W
R154 200K
R173 5K MELF 1W
R174 5K MELF 1W
R175 200K
R182 5K MELF 1W
R183 5K MELF 1W
R184 200K
R185 5K MELF 1W
R186 5K MELF 1W
R187 200K
DS1 BA-CMS-90
DS2 BA-CMS-90
DS3 BA-CMS-90
DS4 BA-CMS-90
DS5 BA-CMS-90
C91 220PF NPO 0805
C97 220PF NPO 0805
C101 220PF NPO 0805
C102 220PF NPO 0805
U42C LT1058SW
U42D LT1058SW
U42A LT1058SW
U42B LT1058SW
LA_Lead
RA_Lead
LL_Lead
V_Lead
U37B MAX327CSE
U37C MAX327CSE
U37D MAX327CSE
U37A MAX327CSE
U44A MAX327CSE
LA_ref
RA_ref
LL_ref
V_ref
RL_ref
U38 CD4051BCM
U43 CD4051BCM
U39B LT1112S8
U39A LT1112S8
U40 AD621AR
C92 .01UF MP 2824
C100 .1UF MP 2824
R137 10K .1% 50PPM
R138 10K .1% 50PPM
R139 10K .1% 50PPM
R140 10K .1% 50PPM
R141 10K .1% 50PPM
R160 10K .1% 50PPM
R161 10K .1% 50PPM
R162 10K .1% 50PPM
R163 10K .1% 50PPM
R143 100K
R149 100K
R172 200K
R176 10K
R178 24.9K
R165 24.9K
R168 10K
R177 10K
D15 MMBD4148
U45A LM339AM
U45B LM339AM
U45C LM339AM
U46 SN74AHC1G08DCK
diag_bw\
U44B MAX327CSE
U44C MAX327CSE
U44D MAX327CSE
ECGX10
ecgX1000
pacer_det
U41A LT1057SB
U41B LT1057SB
R144 9.31K .1% 50PPM
R147 9.31K .1% 50PPM
R148 2.49K
R145 100K
R150 1.62M
R151 178K
R155 1.65K .1% 50PPM
R157 165K .1% 50PPM
R374 20 OHM
C93 .1UF MP 2824
C94 2.2UF MP .4036
C95 1000PF NPO 0805
C96 22UF MP 2824
C98 680PF NPO 0805
C99 .01UF MP 2824
TP7 ECGX1000
R156 32.4K
R164 21.5K
R165 11K
R171 32.4K
R158 10K
R169 10K
LM339AM
+6.5V
+5V
-5V
-6.5V
IVCC
iso_GND
NOTES:
1. LAST USED: C230, D44, DS6, E7, F4, FB5, J24, JP8,K3, L15, Q42, R392, RT2, SF11, T5, TP51,U103, Y4.
2. NOT USED: C221,J18,J22,JP2,JP3,R89,R388.
3. ALL RESISTORS ARE 1/10W, SIZE 0805 UNLESS OTHERWISE SPECIFIED.
IVY BIOMEDICAL SYSTEMS INC.
11 BUSINESS PARK DRIVE
BRANFORD, CT., 06405 USA
(203) 481-4183
DWN MARK TUCCILLO 9/5/01
CHK GP 9/5/01
APR RAM 9/5/01
Title ECG Front End
Size D
Document Number 5143-00-01 (-03 SCHEMATIC)
Rev 24
Date: Friday, May 27, 2005
Sheet 8 of 16



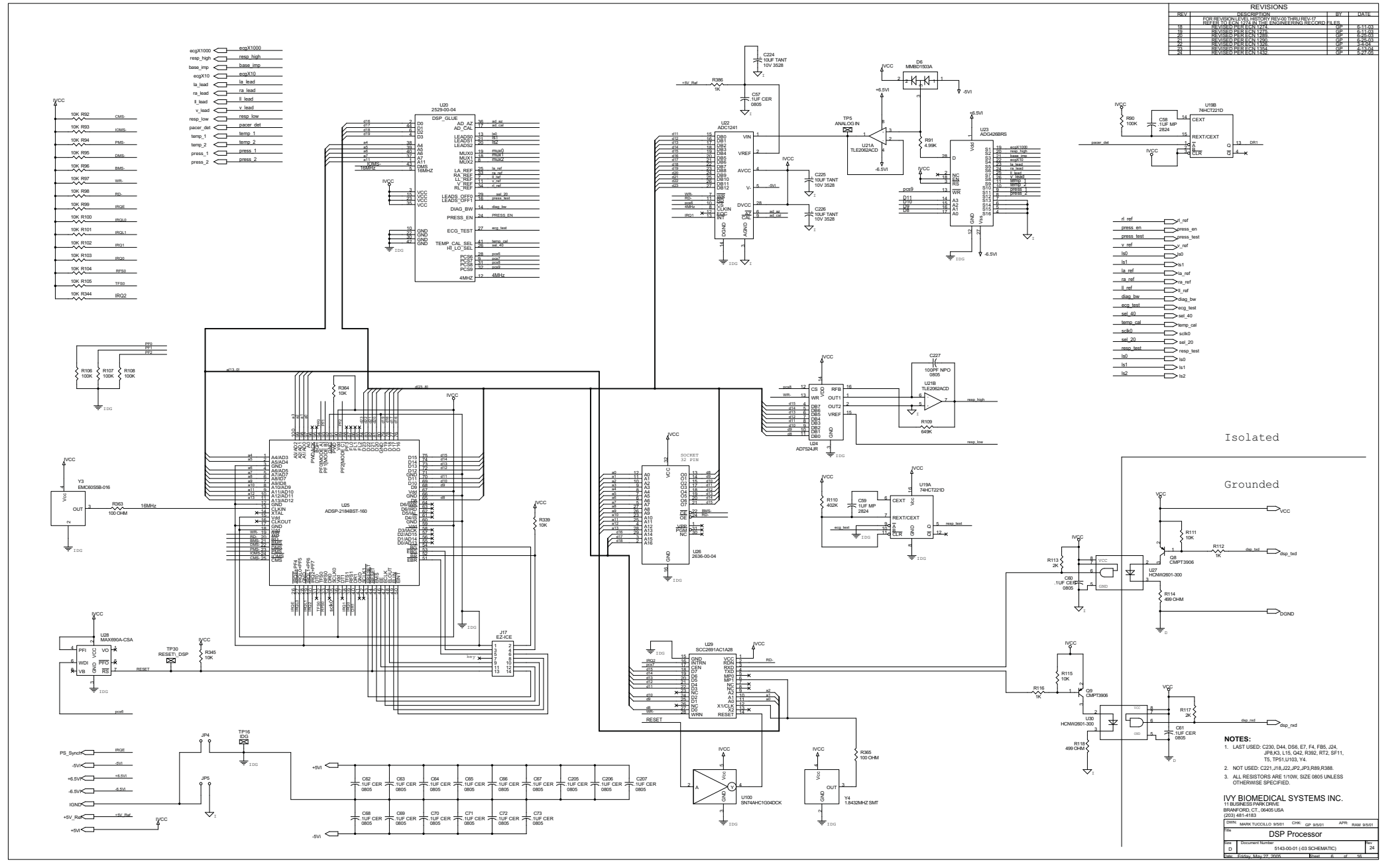
REVISIONS			
REV	DESCRIPTION	BY	DATE
	FOR REVISION LEVEL HISTORY REV-00 THRU REV-17 REFER TO ECN 1274 IN THE ENGINEERING RECORD FILES.		
18	REVISED PER ECN 1274	GP	6-11-03
19	REVISED PER ECN 1275	GP	6-11-03
20	REVISED PER ECN 1289	GP	6-25-03
21	REVISED PER ECN 1290	GP	6-25-03
22	REVISED PER ECN 1328	GP	3-4-04
23	REVISED PER ECN 1354	GP	4-13-04
24	REVISED PER ECN 1432	GP	5-27-05

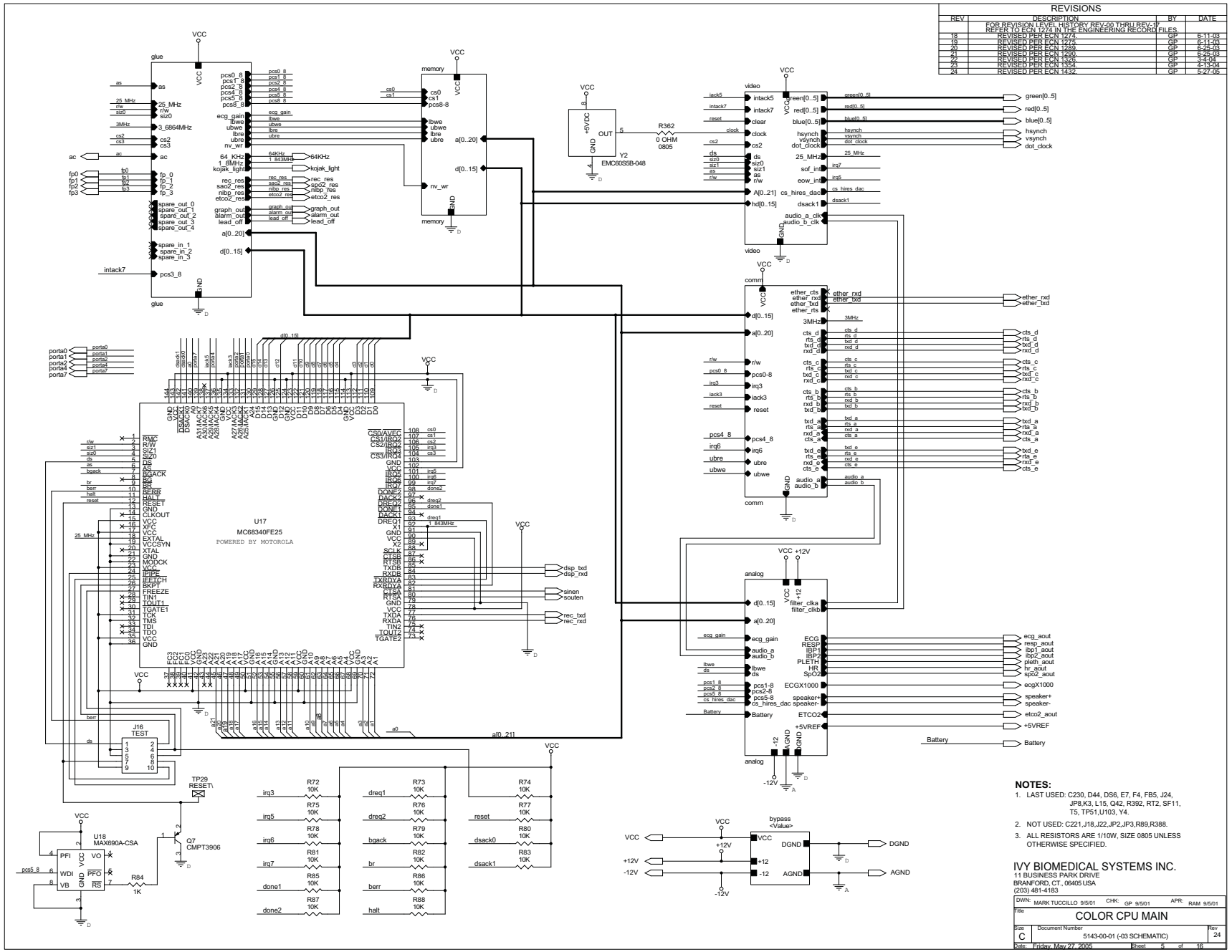
NOTES:

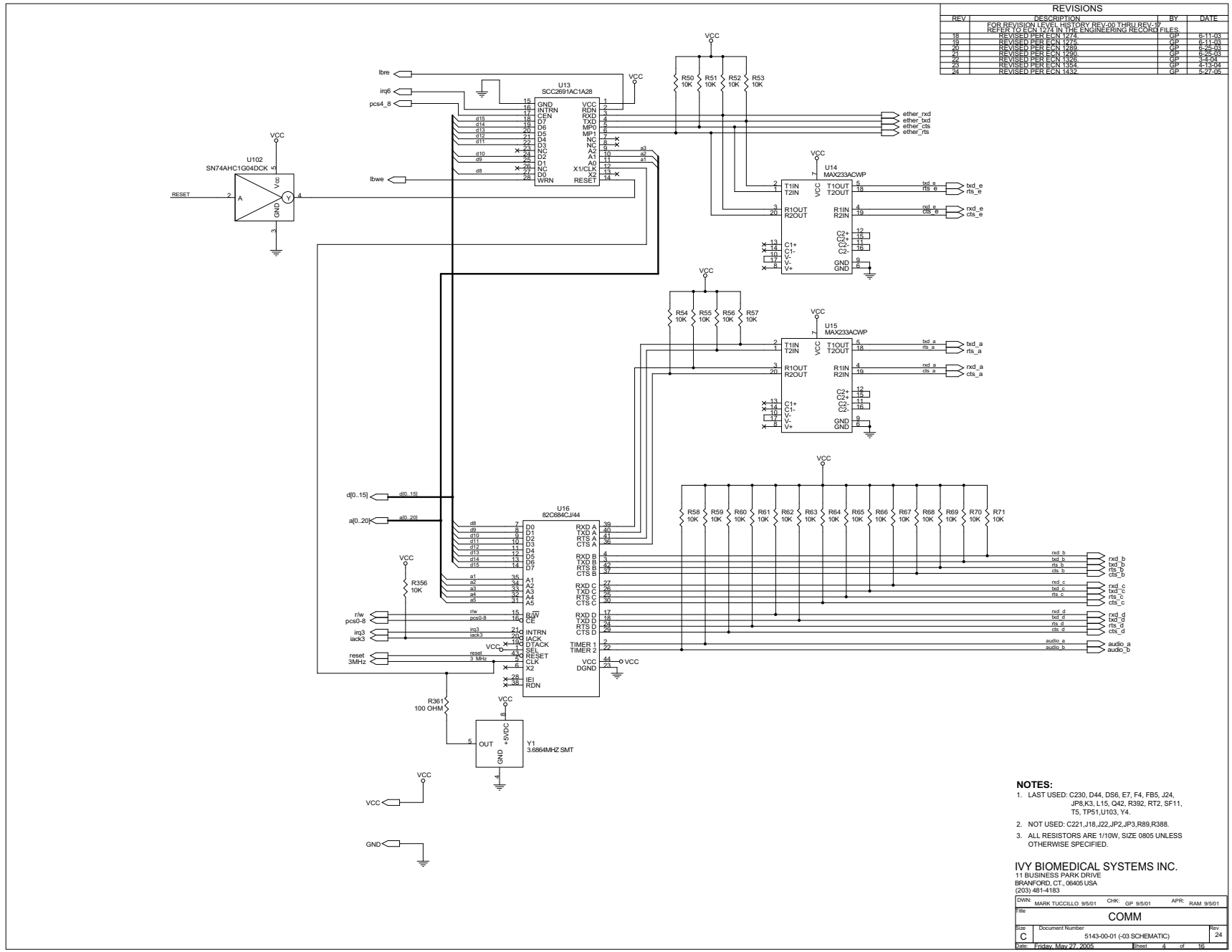
1. LAST USED: C230, D44, DS6, E7, F4, FB5, J24, JP8,K3, L15, Q42, R392, RT2, SF11, T5, TP51,U103, Y4.
2. NOT USED: C221,J18,J22,JP2,JP3,R89,R388.
3. ALL RESISTORS ARE 1/10W, SIZE 0805 UNLESS OTHERWISE SPECIFIED.

IVY BIOMEDICAL SYSTEMS INC.
11 BUSINESS PARK DRIVE
BRANFORD, CT., 06405 USA
(203) 481-4183

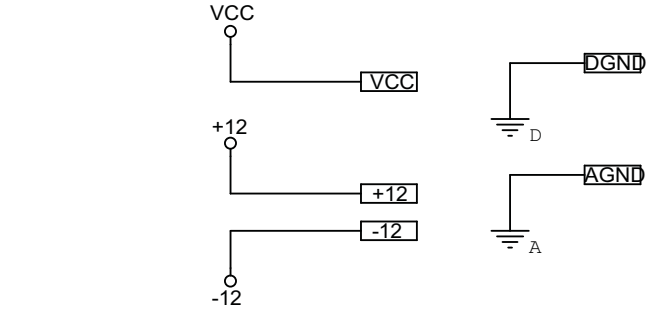
DWN: MARK TUCCILLO 9/5/01	CHK: GP 9/5/01	APR: RAM 9/5/01	
Title: DSP Power Supply			
Size: C	Document Number: 5143-00-01 (-03 SCHEMATIC)		Rev: 24
Date: Friday, May 27, 2005	Sheet 7 of 16		

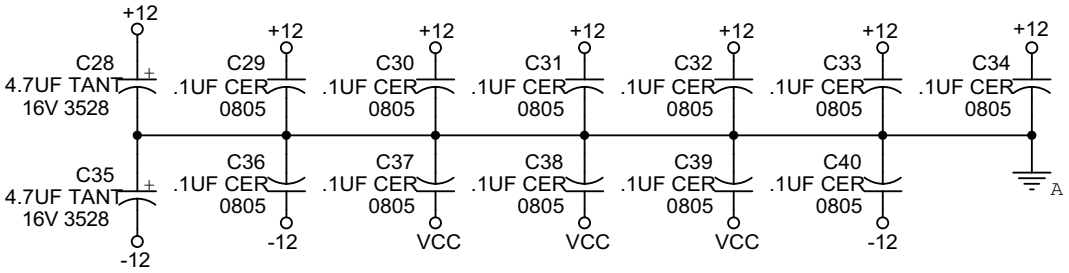

REVISIONS
REV
DESCRIPTION
FOR REVISION LEVEL HISTORY REV.00 THRU REV.17
REFER TO DRAWING 5143-00-01 (.03 ENGINEERING RECORD FILES)
BY
DATE
18 REVISED PER ECN 1275 GP 6-11-03
19 REVISED PER ECN 1275 GP 6-11-03
20 REVISED PER ECN 1280 GP 6-25-03
21 REVISED PER ECN 1290 GP 6-25-03
22 REVISED PER ECN 1305 GP 3-4-04
23 REVISED PER ECN 1354 GP 4-19-04
24 REVISED PER ECN 1492 GP 5-27-05
Isolated
Grounded
NOTES:
1. LAST USED: C230, D44, DS6, E7, F4, FB5, J24, JP8,K3, L15, Q42, R392, RT2, SF11, T5, TP51,U103, Y4.
2. NOT USED: C221,J18,J22,JP2,JP3,R89,R388.
3. ALL RESISTORS ARE 1/10W, SIZE 0805 UNLESS OTHERWISE SPECIFIED.
IVY BIOMEDICAL SYSTEMS INC.
11 BUSINESS PARK DRIVE
BRANFORD, CT., 06405 USA
(203) 481-4183
DWN: MARK TUCCILLO 9/5/01
CHK: GP 9/5/01
APR:
RAM 9/5/01
Title
DSP Processor
Size
D
Document Number
5143-00-01 (-03 SCHEMATIC)
Rev
24
Date: Friday, May 27, 2005
Sheet 6 of 16

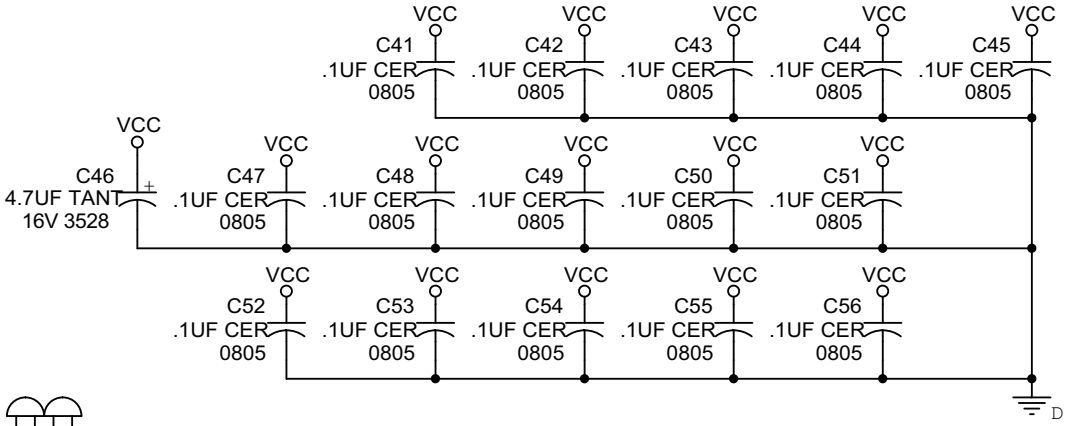

REVISIONS
REV | DESCRIPTION | BY | DATE
FOR REVISION LEVEL HISTORY REV-00 THRU REV-17 REFER TO ECN 1274 IN THE ENGINEERING RECORD FILES.
18 REVISED PER ECN 1274 GP 6-11-03
19 REVISED PER ECN 1275 GP 6-11-03
20 REVISED PER ECN 1289 GP 6-25-03
21 REVISED PER ECN 1290 GP 6-25-03
22 REVISED PER ECN 1326 GP 3-2-04
23 REVISED PER ECN 1354 GP 4-13-04
24 REVISED PER ECN 1432 GP 5-27-05
U17
MC68340FE25
POWERED BY MOTOROLA
U18
MAX690A-CSA
Q7
CMPT3906
Y2
EMC60S5B-048
R362
0 OHM
0805
R84
1K
TP29
RESET\
J16
TEST
glue
memory
video
comm
analog
bypass
<Value>
NOTES:
1. LAST USED: C230, D44, DS6, E7, F4, FB5, J24, JP8,K3, L15, Q42, R392, RT2, SF11, T5, TP51,U103, Y4.
2. NOT USED: C221,J18,J22,JP2,JP3,R89,R388.
3. ALL RESISTORS ARE 1/10W, SIZE 0805 UNLESS OTHERWISE SPECIFIED.
IVY BIOMEDICAL SYSTEMS INC.
11 BUSINESS PARK DRIVE
BRANFORD, CT., 06405 USA
(203) 481-4183
DWN: MARK TUCCILLO 9/5/01 CHK: GP 9/5/01 APR: RAM 9/5/01
Title
COLOR CPU MAIN
Size C
Document Number 5143-00-01 (-03 SCHEMATIC)
Rev 24
Date: Friday, May 27, 2005 Sheet 5 of 16

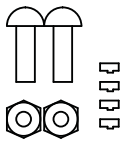

REVISIONS
REV | DESCRIPTION | BY | DATE
FOR REVISION LEVEL HISTORY REV-00 THRU REV-17 REFER TO ECN 1274 IN THE ENGINEERING RECORD FILES
18 REVISED PER ECN 1274 GP 6-11-03
19 REVISED PER ECN 1275 GP 6-11-03
20 REVISED PER ECN 1289 GP 6-26-03
21 REVISED PER ECN 1290 GP 6-26-03
22 REVISED PER ECN 1326 GP 3-2-04
23 REVISED PER ECN 1354 GP 4-13-04
24 REVISED PER ECN 1432 GP 5-27-05
U13 SCC2691AC1A28
U14 MAX233ACWP
U15 MAX233ACWP
U16 82C684CJ/44
U102 SN74AHC1G04DCK
Y1 3.6864MHZ SMT
R356 10K
R361 100 OHM
ether_rxd
ether_txd
ether_cts
ether_rts
bxd_e
rts_e
rxd_e
cts_e
bxd_a
rts_a
rxd_a
cts_a
rxd_b
txd_b
rts_b
cts_b
rxd_c
txd_c
rts_c
cts_c
rxd_d
txd_d
rts_d
cts_d
audio_a
audio_b
lbre
irq6
pcs4_8
lbwe
RESET
r/w
pcs0-8
irq3
iack3
reset
3MHz
d[0..15]
a[0..20]
VCC
GND
NOTES:
1. LAST USED: C230, D44, DS6, E7, F4, FB5, J24, JP8,K3, L15, Q42, R392, RT2, SF11, T5, TP51,U103, Y4.
2. NOT USED: C221,J18,J22,JP2,JP3,R89,R388.
3. ALL RESISTORS ARE 1/10W, SIZE 0805 UNLESS OTHERWISE SPECIFIED.
IVY BIOMEDICAL SYSTEMS INC.
11 BUSINESS PARK DRIVE
BRANFORD, CT., 06405 USA
(203) 481-4183
DWN: MARK TUCCILLO 9/5/01
CHK: GP 9/5/01
APR: RAM 9/5/01
Title: COMM
Size: C
Document Number: 5143-00-01 (-03 SCHEMATIC)
Rev: 24
Date: Friday, May 27, 2005
Sheet 4 of 16

REVISIONS			
REV	DESCRIPTION	BY	DATE
	FOR REVISION LEVEL HISTORY REV-00 THRU REV-17 REFER TO ECN 1274 IN THE ENGINEERING RECORD FILES.		
18	REVISED PER ECN 1274.	GP	6-11-03
19	REVISED PER ECN 1275.	GP	6-11-03
20	REVISED PER ECN 1289.	GP	6-25-03
21	REVISED PER ECN 1290.	GP	6-25-03
22	REVISED PER ECN 1326.	GP	3-4-04
23	REVISED PER ECN 1354.	GP	4-13-04
24	REVISED PER ECN 1432.	GP	5-27-05









NOTES:

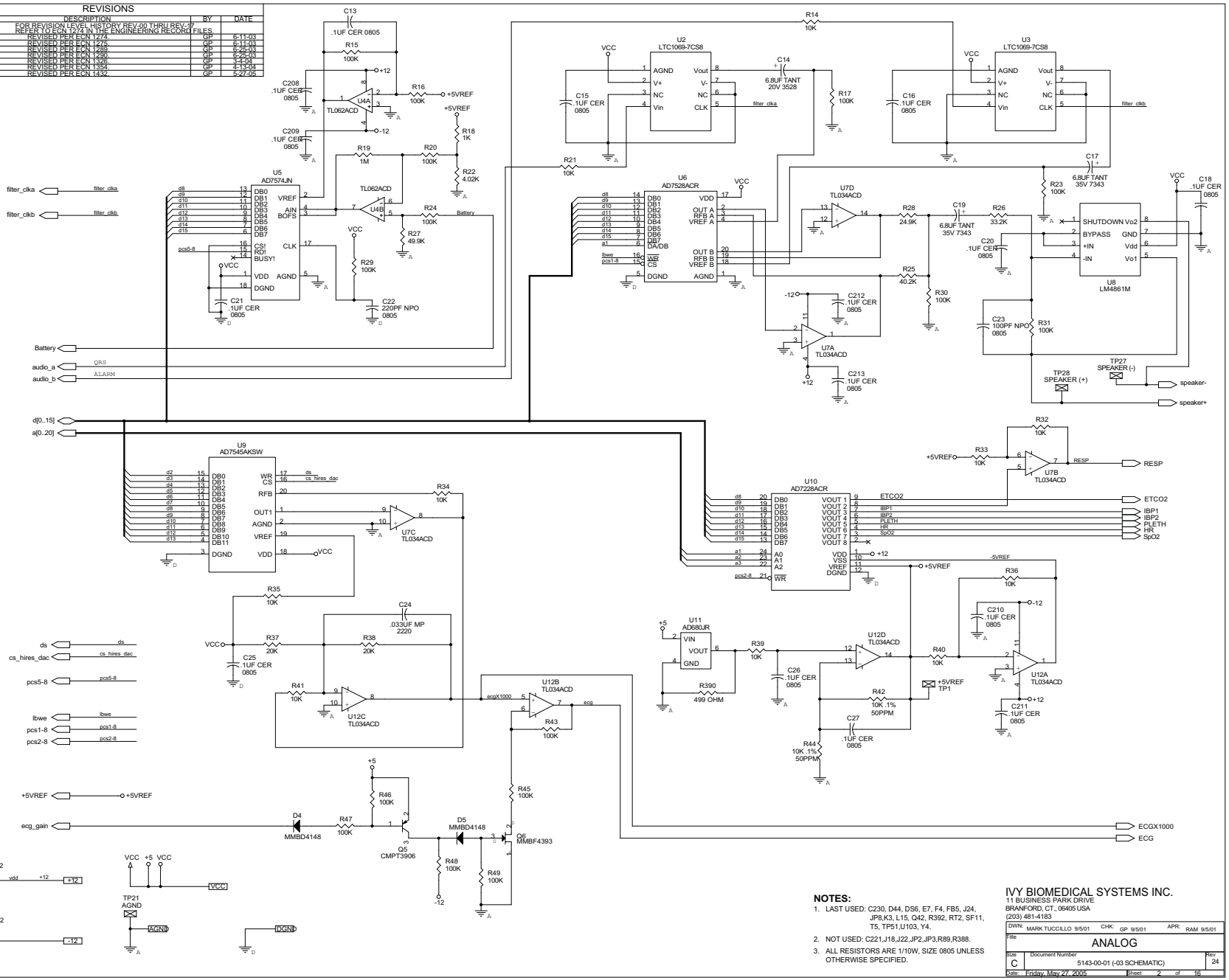
1. LAST USED: C230, D44, DS6, E7, F4, FB5, J24, JP8,K3, L15, Q42, R392, RT2, SF11, T5, TP51,U103, Y4.
2. NOT USED: C221,J18,J22,JP2,JP3,R89,R388.
3. ALL RESISTORS ARE 1/10W, SIZE 0805 UNLESS OTHERWISE SPECIFIED.

IVY BIOMEDICAL SYSTEMS INC.
11 BUSINESS PARK DRIVE
BRANFORD, CT., 06405 USA
(203) 481-4183

DWN: MARK TUCCILLO 9/5/01	CHK: GP 9/5/01	APR: RAM 9/5/01	
Title: BYPASS			
Size: A	Document Number: 5143-00-01 (-03 SCHEMATIC)		Rev: 24
Date: Friday, May 27, 2005	Sheet 3 of 16		

REVISIONS

REV	DESCRIPTION	BY	DATE
	FOR REVISION LEVEL HISTORY REV-00 THRU REV-17 REFER TO ECN 72/4 IN THE ENGINEERING RECORD FILES.		
18	REVISED PER ECN 1274.	GP	6-11-03
19	REVISED PER ECN 1275.	GP	6-11-03
20	REVISED PER ECN 1289.	GP	6-25-03
21	REVISED PER ECN 1290.	GP	6-25-03
22	REVISED PER ECN 1326.	GP	3-4-04
23	REVISED PER ECN 1354.	GP	4-13-04
24	REVISED PER ECN 1432.	GP	5-27-05



NOTES:

1. LAST USED: C230, D44, DS6, E7, F4, FB5, J24, JP8,K3, L15, Q42, R392, RT2, SF11, T5, TP51,U103, Y4.
2. NOT USED: C221,J18,J22,JP2,JP3,R89,R388.
3. ALL RESISTORS ARE 1/10W, SIZE 0805 UNLESS OTHERWISE SPECIFIED.

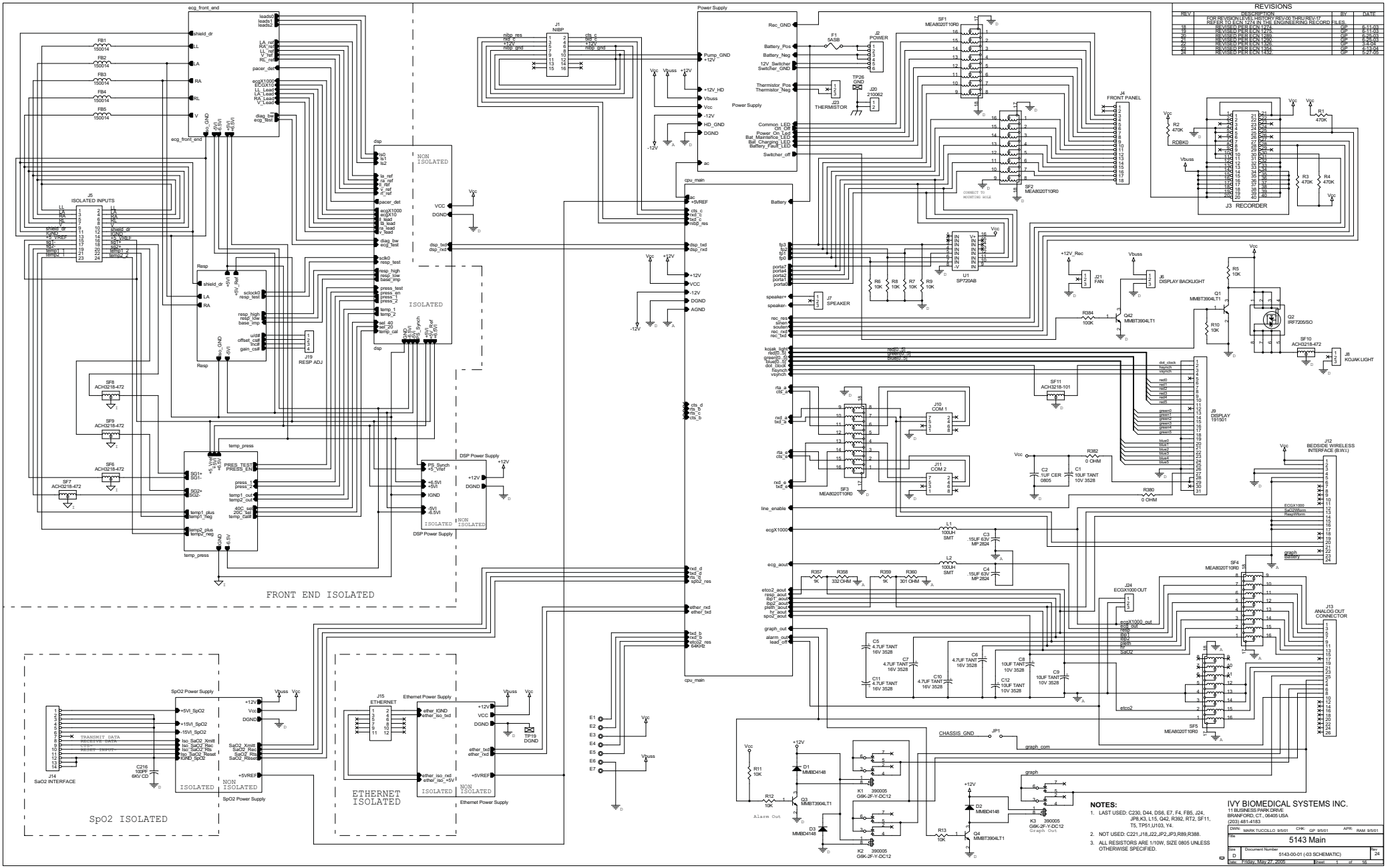
IVY BIOMEDICAL SYSTEMS INC.
11 BUSINESS PARK DRIVE
BRANFORD, CT., 06405 USA
(203) 481-4183

DWN:	CHK:	APR:
MARK TUCCILLO 9/5/01	GP 9/5/01	RAM 9/5/01

Title: ANALOG

Size	Document Number	Rev
C	5143-00-01 (-03 SCHEMATIC)	24

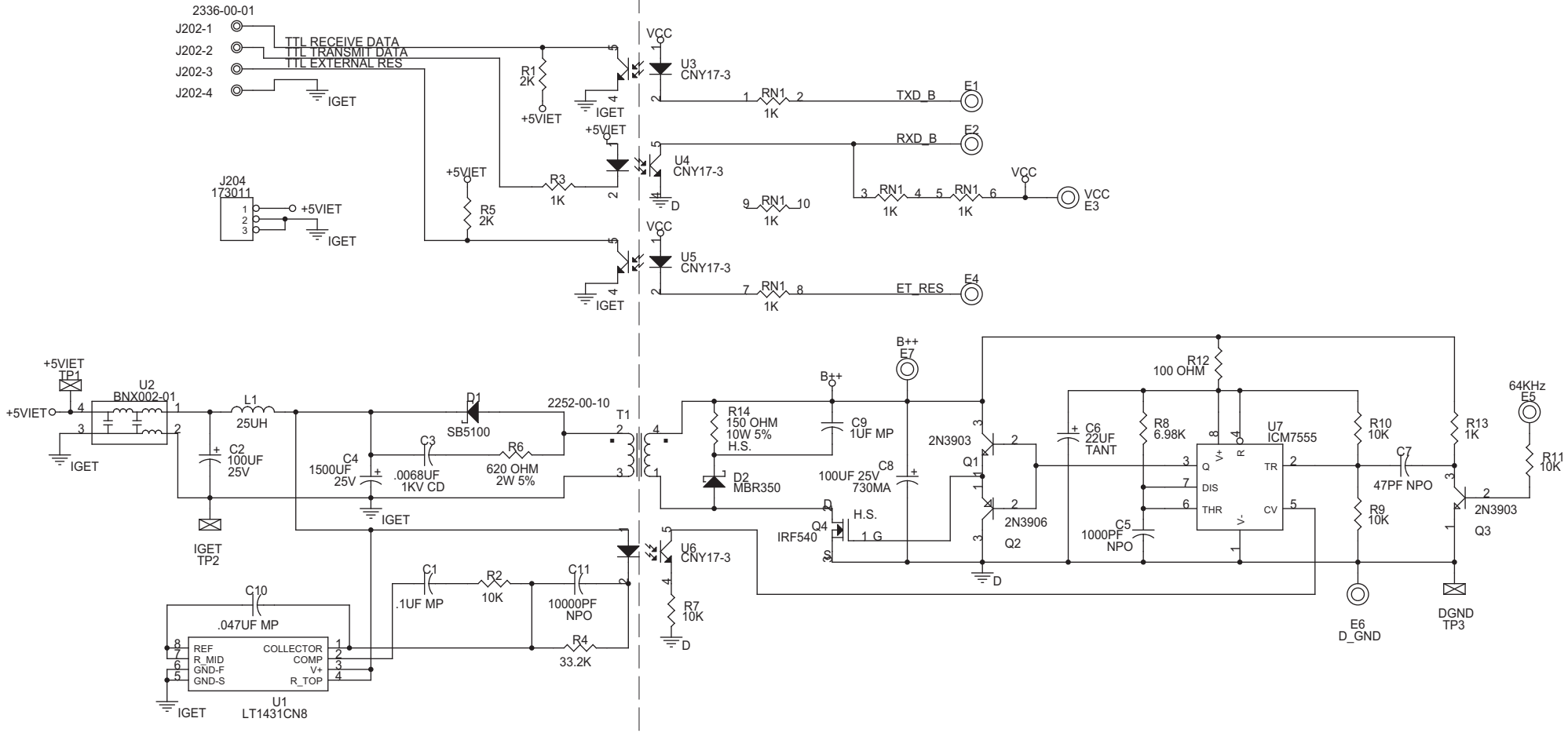
Date: Friday, May 27, 2005 Sheet 2 of 16


REVISIONS
REV | DESCRIPTION | BY | DATE
FOR REVISION LEVEL HISTORY REV.00 THRU REV.17 REFER TO ECN 1274 IN THE ENGINEERING RECORD FILES.
18 REVISED PER ECN 1274 GP 6-11-03
19 REVISED PER ECN 1275 GP 6-11-03
20 REVISED PER ECN 1289 GP 6-25-03
21 REVISED PER ECN 1290 GP 6-25-03
22 REVISED PER ECN 1325 GP 8-4-04
23 REVISED PER ECN 1343 GP 4-19-04
24 REVISED PER ECN 1427 GP 5-27-05
FRONT END ISOLATED
SpO2 ISOLATED
ETHERNET ISOLATED
NOTES:
1. LAST USED: C230, D44, DS6, E7, F4, FB5, J24, JP8,K3, L15, Q42, R392, RT2, SF11, T5, TP51,U103, Y4.
2. NOT USED: C221,J18,J22,JP2,JP3,R89,R388.
3. ALL RESISTORS ARE 1/10W, SIZE 0805 UNLESS OTHERWISE SPECIFIED.
IVY BIOMEDICAL SYSTEMS INC.
11 BUSINESS PARK DRIVE
BRANFORD, CT., 06405 USA
(203) 481-4183
DWN: MARK TUCCILLO 9/5/01 CHK: GP 9/5/01 APR: RAM 9/5/01
5143 Main
Size D Document Number 5143-00-01 (-03 SCHEMATIC) Rev 24
Date: Friday, May 27, 2005 Sheet 1 of 16

REVISIONS			
REV	DESCRIPTION	BY	DATE
01	REVISED PER ECN 691.	GP	8-28-97
02	REVISED PER ECN 709.	GP	11-4-97
03	REVISED PER ECN 957.	GP	6-25-99
04	REVISED PER ECN 1201.	GP	8-9-02

ISOLATED

NON-ISOLATED



NOTES:

1. ALL RESISTORS ARE 1/4W, 1% U.O.S.
2. LAST USED:
3. NOT USED:

IVY BIOMEDICAL SYSTEMS INC.

11 BUSINESS PARK DRIVE
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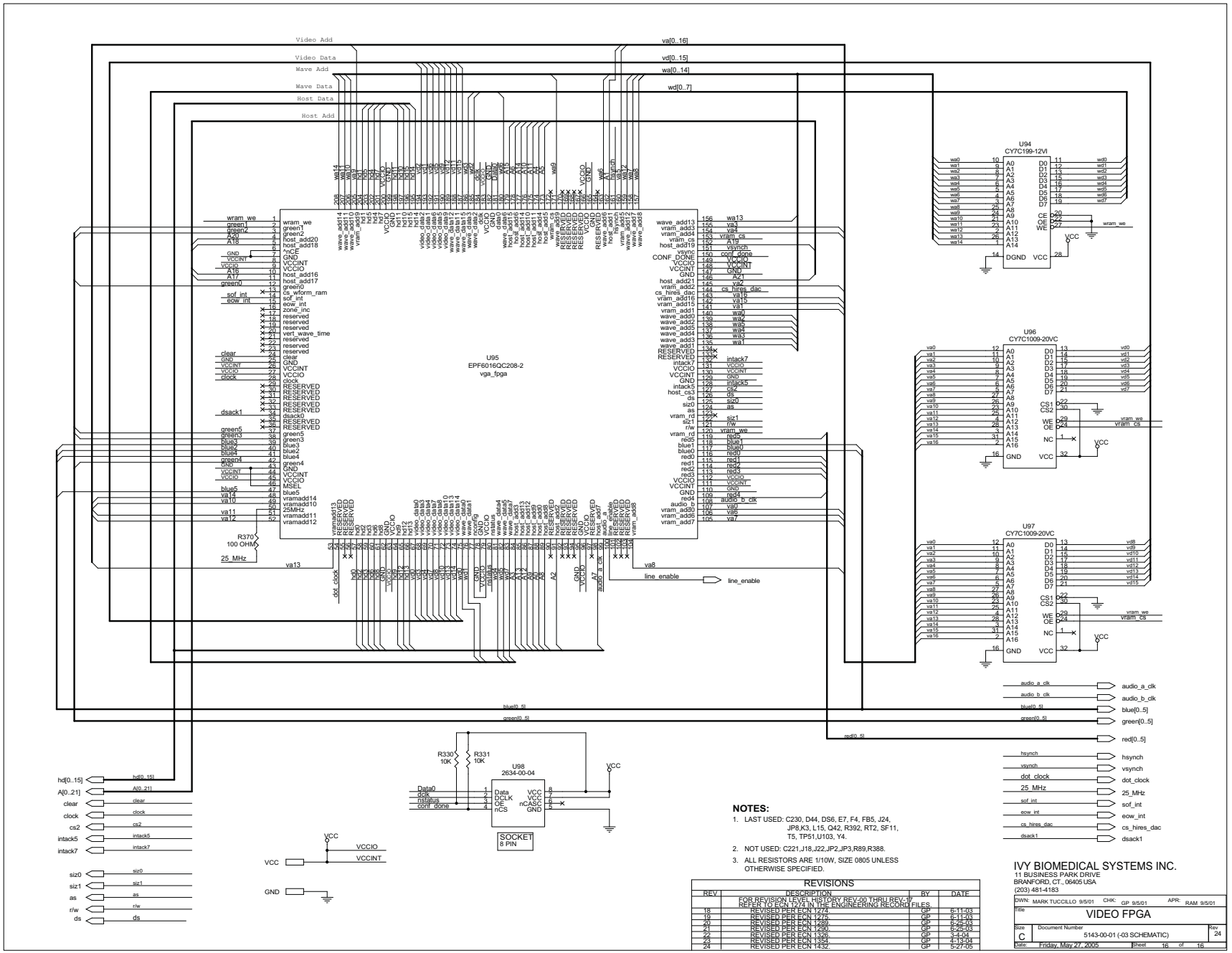
(203) 481-4183

Title: ETCO2 MODULE INTERFACE BOARD ASSEMBLY

Size	Document Number	Rev
B	5108-00-01 (-03 SCHEMATIC)	04

Date: Thursday, March 10, 2005 Sheet 1 of 1



NOTES:

1. LAST USED: C230, D44, DS6, E7, F4, FB5, J24, JP8,K3, L15, Q42, R392, RT2, SF11, T5, TP51,U103, Y4.
2. NOT USED: C221,J18,J22,JP2,JP3,R89,R388.
3. ALL RESISTORS ARE 1/10W, SIZE 0805 UNLESS OTHERWISE SPECIFIED.

REVISIONS

REV	DESCRIPTION	BY	DATE
	FOR REVISION LEVEL HISTORY REV-00 THRU REV-17 REFER TO ECN 1274 IN THE ENGINEERING RECORD FILES.		
18	REVISED PER ECN 1274.	GP	6-11-03
19	REVISED PER ECN 1275.	GP	6-11-03
20	REVISED PER ECN 1289.	GP	6-25-03
21	REVISED PER ECN 1290.	GP	6-25-03
22	REVISED PER ECN 1320.	GP	3-4-04
23	REVISED PER ECN 1354.	GP	4-12-04
24	REVISED PER ECN 1432.	GP	5-27-05

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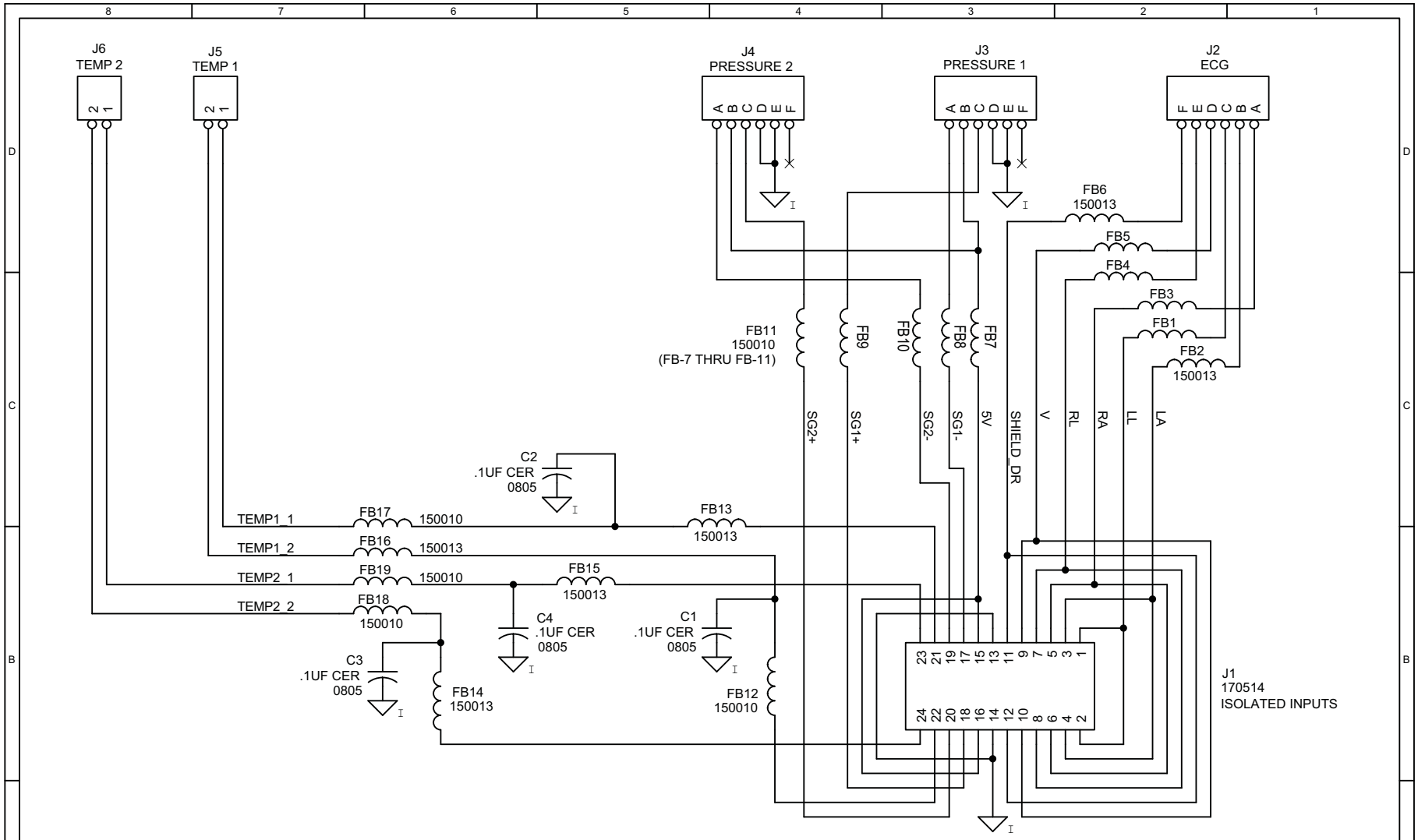
DWN: MARK TUCCILLO 9/5/01 CHK: GP 9/5/01 APR: RAM 9/5/01

Title: VIDEO FPGA

Size: C | Document Number: 5143-00-01 (-03 SCHEMATIC) | Rev: 24

Date: Friday, May 27, 2005 | Sheet 16 of 16



REVISIONS			
REV	DESCRIPTION	BY	DATE
01	REVISED PER ECN 1219.	GP	12-16-02
02	REVISED PER ECN 1220.	GP	12-16-02
03	REVISED PER ECN 1221.	GP	12-16-02

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Title

ISOLATED INPUT BOARD (ECG/RESP,2P & 2T)

Size	Document Number	Rev
A	5144-00-01 (-03 SCHEMATIC)	03

Date: Monday, December 16, 2002 Sheet 1 of 1