Vital-Guard 450C
Patient Monitor
with Masimo SET® SpO₂
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 European Council Directive 93/42/EEC Medical Device Directive when its used in accordance with the instructions provided in the Operation and Maintenance Manual.

Ivy Biomedical Systems, Inc.
11 Business Park Drive
Branford, Connecticut 06405
(203) 481-4183 • (800) 247-4614 • FAX (203) 481-8734
www.ivybiomedical.com e-mail: ivybio@ivybiomedical.com

The following are trademarks of Masimo Corporation: Masimo®, Masimo SET® and LNOP®.
Covered by one or more of the following U.S. Patents: 5,482,036; 5,490,505; 5,632,272; 5,685,299; 5,758,644; 5,769,785; 6,002,952; 6,036,642; 6,067,462; 6,206,830; 6,157,850 and international equivalents. U.S.A. and international patents pending.

Possession or purchase of this device does not convey any express or implied license to use the device with replacement parts which would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device.
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

[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.
SAFETY
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.

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
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<tbody>
<tr>
<td>590170</td>
<td>Three lead patient cable</td>
</tr>
<tr>
<td>590162</td>
<td>Set of three lead wires</td>
</tr>
<tr>
<td>590167</td>
<td>Five lead patient cable</td>
</tr>
<tr>
<td>590168</td>
<td>Set of five lead wires</td>
</tr>
<tr>
<td>590198</td>
<td>Set of three lead wires for prewired electrodes</td>
</tr>
<tr>
<td>590317</td>
<td>Low noise three lead patient cable</td>
</tr>
<tr>
<td>590318</td>
<td>Set of three radiotranslucent lead wires</td>
</tr>
<tr>
<td>590323</td>
<td>Low noise three lead patient cable with 1kohm resistors</td>
</tr>
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</table>

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:
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.

<table>
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<td>RF emissions</td>
<td>Group 1</td>
<td>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.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RF emissions</td>
<td>Class A</td>
<td>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.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
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<tr>
<td>Harmonic emissions</td>
<td>Class A</td>
<td></td>
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<td>Complies</td>
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<td>flicker emissions</td>
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<tr>
<td>IEC 61000-3-3</td>
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### 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.

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<th>Compliance level</th>
<th>Electromagnetic environment – guidance</th>
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<td>Electrostatic discharge (ESD)</td>
<td>±6 kV contact</td>
<td>±6 kV contact</td>
<td>Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
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<tr>
<td>IEC 61000-4-2</td>
<td>±8 kV air</td>
<td>±8 kV air</td>
<td></td>
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<tr>
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<td>±2 kV for power supply lines</td>
<td>±2 kV for power supply lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-4</td>
<td>±1 kV for input/output lines</td>
<td>±1 kV for input/output lines</td>
<td></td>
</tr>
<tr>
<td>Surge</td>
<td>±1 kV differential mode</td>
<td>±250V differential mode</td>
<td>Remove equipment that can cause electrical disturbance from the vicinity of the input/output cables.</td>
</tr>
<tr>
<td>IEC 61000-4-5</td>
<td>±2 kV common mode</td>
<td>±2 kV common mode</td>
<td></td>
</tr>
<tr>
<td>Voltage dips, short interruptions, and voltage variations on power supply input lines</td>
<td>&lt;5 % $U_T$ ($&gt;95$ % dip in $U_T$) for 0.5 cycle</td>
<td>&lt;5 % $U_T$ ($&gt;95$ % dip in $U_T$) for 0.5 cycle</td>
<td>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.</td>
</tr>
<tr>
<td>IEC61000-4-11</td>
<td>40 % $U_T$ (60 % dip in $U_T$) for 5 cycles</td>
<td>40 % $U_T$ (60 % dip in $U_T$) for 5 cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>70 % $U_T$ (30 % dip in $U_T$) for 25 cycles</td>
<td>70 % $U_T$ (30 % dip in $U_T$) for 25 cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt;5 % $U_T$ ($&gt;95$ % dip in $U_T$) for 5 sec cycle</td>
<td>&lt;5 % $U_T$ ($&gt;95$ % dip in $U_T$) for 5 sec cycle</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 A/m</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IEC 61000-4-8</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 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.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF IEC 61000-4-6</td>
<td>3 Vrms 150 kHz to 80 MHz</td>
<td>3 Vrms</td>
<td>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.</td>
</tr>
<tr>
<td>Radiated RF IEC 61000-4-3</td>
<td>3 V/m 80 MHz to 2.5 GHz</td>
<td>3 V/m</td>
<td>d = 1.2√p 80 MHz to 800 MHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>d = 2.3√p 800 MHz to 2.5 GHz</td>
</tr>
</tbody>
</table>

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.
SAFETY

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: SpO2, IBP, Temperature, NIBP, & EtCO2.
- 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
MONITOR DESCRIPTION

Specifications

**ECG**

- **Lead Selection:** Standard Three-Lead: LI, LII, LIII, Five-Lead Option: LI, LII, LIII, aVR, aVL, aVF, V
- **ECG Amplitude 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 CO₂

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)
CO₂ Compensation: Local Barometric Pressure: 500 to 850 Torr (in whole units)
N₂O 0 to 100% (in whole units)
O₂ 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:

<table>
<thead>
<tr>
<th></th>
<th>Adult (mmHg)</th>
<th>Neonatal (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic</td>
<td>60–250</td>
<td>40–130</td>
</tr>
<tr>
<td>Mean</td>
<td>45–235</td>
<td>35–105</td>
</tr>
<tr>
<td>Diastolic</td>
<td>40–220</td>
<td>20–90</td>
</tr>
<tr>
<td>Pulse Rate</td>
<td>30 –180</td>
<td>30 –240</td>
</tr>
</tbody>
</table>

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
- 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/°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
- **SpO₂:**
  - 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, SpO2, 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.
30 minute view: Stored the last 24 hours of heart rate, respiration rate, SpO2 and IBP. Thirty minutes of data are displayed per window.

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°C

Test Mode

ECG: 1 mV/100 ms @ 70 bpm
Respiration: 70 br/min, coincidence check
Invasive Pressures: 150/50 mmHg
Temperatures: 40°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

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sweep Speed</td>
<td>6.25, 12.5, 25, 50 mm/s</td>
</tr>
<tr>
<td>Character Size:</td>
<td></td>
</tr>
<tr>
<td>Large</td>
<td>13x8 mm</td>
</tr>
<tr>
<td>Small</td>
<td>4x3 mm</td>
</tr>
</tbody>
</table>

Recorder

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

Mechanical

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size:</td>
<td></td>
</tr>
<tr>
<td>Height:</td>
<td>11.0 in. (28.0 cm)</td>
</tr>
<tr>
<td>Width:</td>
<td>11.1 in. (28.2 cm)</td>
</tr>
<tr>
<td>Depth:</td>
<td>7.5 in. (19.1 cm)</td>
</tr>
<tr>
<td>Weight:</td>
<td>Basic unit: 12.8 lbs. (5.8 kgs.)</td>
</tr>
</tbody>
</table>

Environmental

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating Temperature Range:</td>
<td>15°C to 35°C</td>
</tr>
<tr>
<td>Storage Temperature Range:</td>
<td>-5°C to 55°C</td>
</tr>
<tr>
<td>Relative Humidity:</td>
<td>0-90% non-condensing</td>
</tr>
</tbody>
</table>

Power Requirements

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

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.

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

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.

NIBP Control Keys

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.

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

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.

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

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

- **ALARM RESET**
  Resets the audible and visual indicators for an alarm that has been activated.

- **PRINT**
  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.

- **TREND**
  Displays Trend data. To define the trend display, see the trend display setup instructions.
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, SpO2, P1, P2, or OFF
ZONE 3: Selectable to display waveforms of RESP, EtCO2, SpO2, P1, P2, or OFF
ZONE 4: Selectable to display waveforms of RESP, EtCO2, SpO2, 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, SpO2, 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.
MONITOR DESCRIPTION

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 CO2 (EtCO2) - To the left of the waveform if the waveform is displayed. Otherwise, at the bottom of display in Zone 5.

Oxygen Saturation (SpO2) 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, SpO2 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, SpO2, respiration rate, and pressure readings.

Review Trend: Graphic and Numeric display of the most recent 24 hours of heart rate, SpO2, 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, SpO2, 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:** 35°C to 45°C in 0.1°C increments
- **Temp Low:** 35°C to 45°C in 0.1°C 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 SpO2:** 50 to 100% in 1% increments
- **Low SpO2:** 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.

<table>
<thead>
<tr>
<th>Priority</th>
<th>SCHEME 1</th>
<th>SCHEME 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Color</td>
<td>Audio Type</td>
</tr>
<tr>
<td>High</td>
<td>Red</td>
<td>Rapid Beeps</td>
</tr>
<tr>
<td>Medium</td>
<td>Yellow</td>
<td>Slower Beeps</td>
</tr>
<tr>
<td>SpO2 High</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Low</td>
<td>White</td>
<td>Longest Beeps</td>
</tr>
</tbody>
</table>

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, SpO2, 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 guarantee 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.

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, SpO2, P1/P2, or NIBP menus. See the menu structure diagram below.

When the main menu is displayed, press EXIT to return to normal display.
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.
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 CO₂ is to be monitored, connect the Sensor cable to the ETCO₂ 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.**

<table>
<thead>
<tr>
<th>Zone 1</th>
<th>Zone 2</th>
<th>Zone 3</th>
<th>Zone 4</th>
<th>Zone 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECG</td>
<td>Off</td>
<td>Off</td>
<td>Off</td>
<td>Off</td>
</tr>
<tr>
<td>Resp/CO₂</td>
<td>Resp/CO₂</td>
<td>SpO₂ (Pleth)</td>
<td>Resp/CO₂</td>
<td>Resp/CO₂</td>
</tr>
<tr>
<td>SpO₂ (Pleth)</td>
<td>SpO₂ (Pleth)</td>
<td>SpO₂</td>
<td>SpO₂</td>
<td>SpO₂</td>
</tr>
<tr>
<td>P1</td>
<td>P1</td>
<td>NIBP</td>
<td>P1</td>
<td>NIBP</td>
</tr>
<tr>
<td>P2</td>
<td>P2</td>
<td>P1</td>
<td>P2</td>
<td>P1 Expanded</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>P2 Expanded</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>P1/P2 Expanded</td>
</tr>
</tbody>
</table>

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.
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, SpO₂, 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 SpO₂ trend, if the SpO₂ 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.
Review Trend Displays

Review trend collects the most recent 24 hours of heart rate, SpO₂, 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, SpO₂, 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.
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.
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)

RESPERATION
Resp: Impedance
Apnea delay: 20 sec
Coincidence: ON
RR limits (60-10)
SpO2
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

EtCO2
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.

<table>
<thead>
<tr>
<th>Status of the Battery</th>
<th>Charged LED</th>
<th>Charging LED</th>
<th>Battery Fault LED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Battery Absent</td>
<td>OFF</td>
<td>OFF</td>
<td>ON</td>
</tr>
<tr>
<td>Pre-charge qualification</td>
<td>OFF</td>
<td>FLASHING</td>
<td>OFF</td>
</tr>
<tr>
<td>Fast charging</td>
<td>OFF</td>
<td>ON</td>
<td>OFF</td>
</tr>
<tr>
<td>Maintenance charging</td>
<td>ON</td>
<td>OFF</td>
<td>OFF</td>
</tr>
<tr>
<td>*Charge Pending (Temperature out of range)</td>
<td>X</td>
<td>X</td>
<td>FLASHING</td>
</tr>
<tr>
<td>**Fault</td>
<td>X</td>
<td>X</td>
<td>ON</td>
</tr>
</tbody>
</table>

*If the temperature of the battery exceeds 116 °F (47 °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).
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.

   ![Diagram of paper eject button]

   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.

   ![Diagram of paper alignment]

Press Here
Print Head
Pinch Roller
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, ETCO₂, SpO₂ (Pleth), P1, and P2. Channel 2 can also be set to OFF. Whenever ETCO₂ is being monitored, the ETCO₂ 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.

<table>
<thead>
<tr>
<th>Type of Alarm</th>
<th>Traces Printed</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASYSTOLE</td>
<td>Single-trace ECG</td>
</tr>
<tr>
<td>HR</td>
<td>Single-trace ECG, SpO₂ (Pleth), P1, or P2 (based on HR source)</td>
</tr>
<tr>
<td>NO PULSE</td>
<td>Single-trace SpO₂ (Pleth), P1, or P2 (based on HR source)</td>
</tr>
<tr>
<td>APNEA</td>
<td>ECG, Respiration</td>
</tr>
<tr>
<td>COINCIDENCE</td>
<td>ECG, Respiration</td>
</tr>
<tr>
<td>RR</td>
<td>ECG, Respiration</td>
</tr>
<tr>
<td>SpO₂</td>
<td>ECG, SpO₂ (Pleth)</td>
</tr>
<tr>
<td>NIBP</td>
<td>Single-trace ECG</td>
</tr>
<tr>
<td>IBP1</td>
<td>ECG, P1</td>
</tr>
<tr>
<td>IBP2</td>
<td>ECG, P2</td>
</tr>
</tbody>
</table>
RECORD OPERAION

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 trend, select [PRINT TREND] from the [RECORDE 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:

<table>
<thead>
<tr>
<th>Time</th>
<th>Vertical Scaling</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 hour</td>
<td>5 min/cm</td>
</tr>
<tr>
<td>8 hours</td>
<td>30 min/cm</td>
</tr>
<tr>
<td>12 hours</td>
<td>45 min/cm</td>
</tr>
<tr>
<td>24 hours</td>
<td>90 min/cm</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>View Time</th>
<th>Vertical Scaling</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 Hour View</td>
<td>0.5 hr / cm</td>
</tr>
<tr>
<td>30 Minute View</td>
<td>2.5 min / cm</td>
</tr>
</tbody>
</table>

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

**5/11/99 10:40**

| ECG HR  | 60 BPM |
| RESP   | 30 Br/PM |
| Sp02   | 100 %  |
| T1     | 23.8 C  |
| T2     | 23.7 C  |
| NIBP PPR | 58 BPM |
| NIBP   | 126/74 (92) mmHg |
| P1     | 119/80 (93) mmHg |
| P2     | 30/10 (18) mmHg |

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

**5/11/99 10:43**

| ECG HR  | 60 BPM |
| RESP   | 30 Br/PM |
| Sp02   | 100 %  |
| T1     | 23.8 C  |
| T2     | 23.8 C  |
| NIBP PPR | 58 BPM |
| NIBP   | 126/74 (92) mmHg |
| P1     | 119/80 (93) mmHg |
| P2     | 30/10 (18) mmHg |

Direct Mode: ECG on Channel 1 and SpO2 (Pleth) on Channel 2
5/11/99  10:44
ECG HR  60 BPM
RESP  30 Br/PM
SpO2  99 %
T1  23.8 C
T2  23.8 C
NIBP PPR 58 BPM
NIBP 126/74  (92) mmHg
P1  119/80  (93) mmHg
P2  30/10  (18) mmHg

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

5/11/99  10:45
ECG HR  60 BPM
RESP  30 Br/PM
SpO2  98 %
T1  23.9 C
T2  23.8 C
NIBP PPR 58 BPM
NIBP 126/74  (92) mmHg
P1  119/80  (93) mmHg
P2  30/10  (18) mmHg

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

5/11/99  10:46
ECG HR  60 BPM
RESP  30 Br/PM
SpO2  99 %
T1  24.0 C
T2  23.8 C
NIBP PPR 58 BPM
NIBP 126/74  (92) mmHg
P1  119/80  (93) mmHg
P2  30/10  (18) mmHg

Direct Mode: ECG on Channel 1 and Channel 2 off
Delayed Mode: ECG on Channel 1 and Channel 2 off

CRG Mode

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**

![Warning Symbol]

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

ECG Patient connections are electrically isolated Type CF ![Heart Symbol]. 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.

![Typical Electrode Placement during Surgical Procedure]

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 MONITORING

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 Menus Diagram]

**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/CO₂] 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/CO₂] 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/CO₂] 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.
General Description

The Ivy Model 450C monitor uses NonDispersive InfraRed (NDIR) gas measurement to determine CO₂ 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 (CO₂). 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 CO₂ 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
**ETCO2 MONITORING**

*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 CO₂ 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 CO₂ IR Detector’s output is relative to the CO₂ concentration in the Airway Adapter, while the reference channel IR Detector is insensitive to CO₂ 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.
ETCO₂ MONITORING

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 CO₂ 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 CO₂ molecules in the IR path, without airway adapter pressure compensation, changes in gas pressure would appear as changes in CO₂ concentration.

Typically, the monitor measures CO₂ 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 CO₂ 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 – N₂O, 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 CO₂ and reference channel IR filters reduces the “cross gas interference” effect.

Non-IR Absorbing Gases Present – The sample gas might also contain O₂, N₂O, or N₂. Although O₂ and N₂ don’t absorb IR, they can create NDIR measurement problems via “collision line broadening.”

The monitor uses assumed values for O₂ and N₂O and uses these values to compensate for “collision line broadening.” The default values are 21.0% O₂ and 0.0% N₂O. Different values can be entered and stored in the Sensor Head.

NOTE: When using a calibration gas for span calibration or troubleshooting, O₂ and N₂O 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 CO₂ detector voltage represents 0.00% CO₂ gas concentration and what other voltage represents full scale CO₂ 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% CO₂ 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 CO₂ measurements are between these two values. The factory characterization of each unit includes the calculation of the system’s CO₂ 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 CO₂ 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 CO₂ 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.
ETCO₂ MONITORING

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 CO₂ 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 CO₂, 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 CO₂ 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 ETCO₂ input on the monitor.

3. Verify the presence of a CO₂ 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/CO₂], then select [RESP] so that CO₂ 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.
ETCO₂ MONITORING

Compensation Settings

As described earlier in this section, settings are available for entering barometric pressure, N₂O, and O₂ 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, N₂O = 0.0%, and O₂ = 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/CO₂], then select [RESP] so that CO₂ 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.

N₂O Compensation

1. Press the PATIENT SETUP key on the monitor to display the Main Menu, select [RESP/CO₂], then select [RESP] so that CO₂ menu is displayed. Then select [SETTINGS].
2. Select [NEXT SETTING] until N₂O is displayed.
3. Use the [N₂O ⧧ and ⬇] selections to set the N₂O to the desired value.
4. Press the EXIT key to return to the normal display.

O₂ Compensation

1. Press the PATIENT SETUP key on the monitor to display the Main Menu, select [RESP/CO₂], then select [RESP] so that CO₂ menu is displayed. Then select [SETTINGS].
2. Select [NEXT SETTING] until O₂ is displayed.
3. Use the [O₂ ⧧ and ⬇] selections to set the O₂ 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/CO2], then select [RESP] so that CO2 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.

**CO2 Alarm Limits**

1. Press the **ALARM SETUP** key to display the alarm limits menu.
2. If necessary select [PARAMETER] until ETCO₂ is displayed.
3. Use the [HIGH ▲ and ▼] selections to set the high CO₂ limit.
4. Use the [LOW ▲ and ▼] selections to set the low CO₂ 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/CO2], then select [RESP] to set respiration to OFF.
2. Press **EXIT** to return to the normal display.
ETCO₂ MONITORING

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/CO₂], then select [RESP] so that CO₂ 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% CO₂ 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% CO₂ 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.
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 user's 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.

<table>
<thead>
<tr>
<th>Site Label</th>
<th>SYS</th>
<th>DIAS</th>
<th>MEAN</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>High</td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td>P1</td>
<td>150</td>
<td>80</td>
<td>100</td>
</tr>
<tr>
<td>ART1</td>
<td>150</td>
<td>80</td>
<td>100</td>
</tr>
<tr>
<td>CVP1</td>
<td>-10</td>
<td>10</td>
<td>-10</td>
</tr>
<tr>
<td>PA1</td>
<td>150</td>
<td>80</td>
<td>100</td>
</tr>
<tr>
<td>ICP1</td>
<td>20</td>
<td>4</td>
<td>20</td>
</tr>
<tr>
<td>UAC1</td>
<td>100</td>
<td>40</td>
<td>60</td>
</tr>
<tr>
<td>UVC1</td>
<td>20</td>
<td>4</td>
<td>20</td>
</tr>
</tbody>
</table>

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):

<table>
<thead>
<tr>
<th>Site Label</th>
<th>Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1</td>
<td>0 to 240 mmHg</td>
</tr>
<tr>
<td>ART1</td>
<td>0 to 240 mmHg</td>
</tr>
<tr>
<td>CVP1</td>
<td>-30 to 30 mmHg</td>
</tr>
<tr>
<td>PA1</td>
<td>0 to 240 mmHg</td>
</tr>
<tr>
<td>ICP1</td>
<td>-30 to 30 mmHg</td>
</tr>
<tr>
<td>UAC1</td>
<td>0 to 120 mmHg</td>
</tr>
<tr>
<td>UVC1</td>
<td>0 to 60 mmHg</td>
</tr>
</tbody>
</table>
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 SpO₂. 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 SpO₂ 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.

\[
S(660) = \frac{AC(660)}{DC(660)}
\]

\[
S(940) = \frac{AC(940)}{DC(940)}
\]

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

\[
R = \frac{S(660)}{S(940)}
\]

The value of R is used to find the saturation SpO₂ 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:

\[
S(660) = S1 + N1
\]

\[
S(940) = S2 + N2
\]

\[
R = \frac{S1}{S2}
\]

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 sought 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 SpO₂ value. This entire sequence is repeated once every two seconds on the most recent four seconds of raw data. The Model 450C SpO₂ 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 considered 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 SpO₂ 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.
**SpO2 Alarm Limits**

1. Press the ALARM SETUP key to display the alarm limits menu.
2. Use the [PARAMETER] selection to display SpO2 % limit settings.
3. Use the [HIGH ⬆ and ⬇️] selections to set the high SpO2 % limit.
4. Use the [LOW ⬆ and ⬇️] selections to set the low SpO2 % 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 [SpO2] to display the SpO2 menu.
2. Use the [SpO2 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 SpO2 limit – set to 100.
2. Low SpO2 limit – set to 90.
3. Averaging – set to 8 sec.
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 SpO₂ 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 (methemoglobin) indocyanine 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; SaO2; 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 cause 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 sleeve 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.
**NIBP MONITORING**

**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 ETCO2:** 10 to 100 Torr in 2 Torr increments  
**Low ETCO2:** 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 SpO2:** 50 to 100% in 1% increments  
**Low SpO2:** 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 SpO₂ 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.

EtCO₂ 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).
MAINTENANCE AND CLEANING

**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

ETCO₂

Adult Airway Adapter  590186
Pediatric/Neonatal Airway Adapter  590188
ETCO₂ Sensor with Span Check 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
## ACCESSORIES

### 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
## ACCESSORIES

### SpO₂ Reusable Sensors

- Adult LNOP DC-1 Finger Sensor, Reusable 590227

### SpO₂ 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

### SpO₂ Patient Cables

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

### SpO₂ 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

<table>
<thead>
<tr>
<th>Pin</th>
<th>Signal</th>
<th>Output</th>
</tr>
</thead>
</table>
| 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 peak-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   | SpO2            | 50 mV/% SpO₂ 100% max, 100% = 5 V |
| 9   | No Connection   | Ground |
| 10  | GROUND          | Ground |
| 11  | EtCO₂           | 50 mV/mmHg  
38 mmHg = 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       | Relay closure for Nurse Call option |
| 15  | UNIT ON         | Ground |
| 16  | NURSE CALL      | High +5 V (>2.4 V) when a lead off alarm is present |
| 17  | N.C. COMMON     | High +5 V (>2.4 V) when an alarm is present |
| 18-25| No Connection  | Ground |

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

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

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)

<table>
<thead>
<tr>
<th>Pin</th>
<th>Signal</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>TRANSMIT DATA</td>
</tr>
<tr>
<td>2</td>
<td>SIGNAL GROUND</td>
</tr>
<tr>
<td>3</td>
<td>RECEIVE DATA</td>
</tr>
<tr>
<td>4</td>
<td>Not Used</td>
</tr>
<tr>
<td>5</td>
<td>Not Used</td>
</tr>
<tr>
<td>6</td>
<td>SIGNAL GROUND</td>
</tr>
<tr>
<td>7</td>
<td>Not Used</td>
</tr>
<tr>
<td>8</td>
<td>Not Used</td>
</tr>
</tbody>
</table>
## 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.

<table>
<thead>
<tr>
<th>FUNCTION</th>
<th>OPTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECG</td>
<td>3 LEAD 60Hz 3 LEAD 50Hz 5 LEAD 60Hz 5 LEAD 50Hz</td>
</tr>
<tr>
<td>RESP</td>
<td>ABSENT IMPEDANCE CO₂ IMP + CO₂</td>
</tr>
<tr>
<td>SpO₂</td>
<td>ABSENT NELLCOR MP204 MASIMO NELLCOR MP405</td>
</tr>
<tr>
<td>NIBP</td>
<td>ABSENT COLIN</td>
</tr>
<tr>
<td>TEMP</td>
<td>ABSENT SINGLE DUAL</td>
</tr>
<tr>
<td>INVASIVE BP</td>
<td>ABSENT SINGLE DUAL</td>
</tr>
<tr>
<td>RECORDER</td>
<td>ABSENT PRESENT</td>
</tr>
<tr>
<td>COM 1</td>
<td>ABSENT HTS820TC HTS820 THERMALINK</td>
</tr>
<tr>
<td>COM2/ETHERNET</td>
<td>ABSENT CPC REV C ANSAR REV B</td>
</tr>
<tr>
<td>AUDIO OFF FEATURE</td>
<td>ABSENT PRESENT</td>
</tr>
<tr>
<td>LATCHING ALARMS</td>
<td>ABSENT PRESENT</td>
</tr>
<tr>
<td>PRIORITY ALARMS</td>
<td>ABSENT SCHEME 1 SCHEME 2</td>
</tr>
<tr>
<td>INITIAL LIMITS</td>
<td>DEFAULTS STORED</td>
</tr>
<tr>
<td>TEMP UNITS</td>
<td>DEGREES F DEGREES C</td>
</tr>
<tr>
<td>PRESSURE UNITS</td>
<td>KPA MMHG</td>
</tr>
<tr>
<td>PRESSURE SITE LABELS</td>
<td>ABSENT PRESENT</td>
</tr>
<tr>
<td>CO₂ UNITS</td>
<td>KPA MMHG PERCENT</td>
</tr>
<tr>
<td>ALARM TONE</td>
<td>3.0 KHZ 3.5KHZ 4.0KHZ</td>
</tr>
<tr>
<td>TAB RETENTION</td>
<td>NONE ONE HOUR PERMANENT TWO HOUR</td>
</tr>
<tr>
<td>DATE FORMAT</td>
<td>MM/DD/YYYY DD/ MM/YYYY</td>
</tr>
<tr>
<td>KEYPAD TYPE</td>
<td>17 KEYS 20 NO LIGHT 20 + LIGHT</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Setting</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HR high alarm limit</td>
<td>150</td>
</tr>
<tr>
<td>HR low alarm limit</td>
<td>50</td>
</tr>
<tr>
<td>Lead select</td>
<td>I</td>
</tr>
<tr>
<td>Filter</td>
<td>ON</td>
</tr>
<tr>
<td>ECG Size</td>
<td>10 mm/mV</td>
</tr>
<tr>
<td>Alarms</td>
<td>ON (ALARMS OFF message not displayed)</td>
</tr>
</tbody>
</table>

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, SpO₂ reading, pulse rate, bar indicator, and audio tone.
TESTING AND TROUBLESHOOTING

ETCO₂ Test

Equipment Required

- EtCO₂ sensor with cable.

Test Procedure

1. Make sure the EtCO₂ waveform is displayed in either zone 2, 3, or 4.
2. Check for the NO SENSOR message to be displayed.
3. Plug in the EtCO₂ 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 EtCO₂ value and waveform to be within the percentage value of the Barometric Pressure (760mmHg) printed on the span check cell.
   \[(\text{Span Check Value} = \%\text{value} \times \frac{760}{100})\]

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.

![Diagram of isolation and leakage tests](image)

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

<table>
<thead>
<tr>
<th>Error</th>
<th>Meaning</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The EPROM checksum test has failed.</td>
<td>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).</td>
</tr>
<tr>
<td>2</td>
<td>The static RAM test has failed.</td>
<td>Replace Mother Board (5143-00-01).</td>
</tr>
<tr>
<td>3</td>
<td>The non-volatile (clock chip) RAM test has failed.</td>
<td>Replace Lithium Battery (330115) or replace Mother Board (5143-00-01).</td>
</tr>
<tr>
<td>4</td>
<td>An undefined interrupt has been detected.</td>
<td>Replace Mother Board (5143-00-01)</td>
</tr>
<tr>
<td>5</td>
<td>A system timing error has been detected.</td>
<td>Replace Mother Board (5143-00-01)</td>
</tr>
<tr>
<td>6</td>
<td>No DSP data has been received.</td>
<td>Replace Mother Board (5143-00-01).</td>
</tr>
<tr>
<td>7</td>
<td>A DSP communication error (framing, overrun, etc) has been detected.</td>
<td>Replace Mother Board (5143-00-01)</td>
</tr>
<tr>
<td>8</td>
<td>Bad DSP data has been received (ie: a bad header byte).</td>
<td>Replace Mother Board (5143-00-01)</td>
</tr>
<tr>
<td>9</td>
<td>An unknown error has been detected.</td>
<td>Replace Mother Board (5143-00-01)</td>
</tr>
</tbody>
</table>
## Replacement Parts

### Printed Circuit Boards

<table>
<thead>
<tr>
<th>Part</th>
<th>Ivy Part Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>450C Monitor Mother Board</td>
<td>5143-00-01</td>
</tr>
<tr>
<td>Isolated Input Board (ECG/RESP, 2Temps &amp; 2Press)</td>
<td>5144-00-01</td>
</tr>
<tr>
<td>Isolated Input Board (ECG/RESP)</td>
<td>5144-01-01</td>
</tr>
<tr>
<td>Isolated Input Board (ECG/RESP &amp; 2Temps)</td>
<td>5144-02-01</td>
</tr>
<tr>
<td>Isolated Input Board (ECG/RESP &amp; 2Press)</td>
<td>5144-03-01</td>
</tr>
<tr>
<td>EtCO₂ Interface Board</td>
<td>5108-00-01</td>
</tr>
</tbody>
</table>

### Modules and Assemblies

<table>
<thead>
<tr>
<th>Part</th>
<th>Ivy Part Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Replacement Battery</td>
<td>110007</td>
</tr>
<tr>
<td>EOS Power Supply 60W</td>
<td>580025</td>
</tr>
<tr>
<td>Masimo SpO₂ Module (MS-3)</td>
<td>580022</td>
</tr>
<tr>
<td>Colin M2000 NIBP Module</td>
<td>580024</td>
</tr>
<tr>
<td>EtCO₂ Signal Processor Board</td>
<td>580011</td>
</tr>
<tr>
<td>EtCO₂ Power Board</td>
<td>580012</td>
</tr>
<tr>
<td>LSI Telemetry Transmitter Module Kit</td>
<td>580016</td>
</tr>
<tr>
<td>Ethernet Module</td>
<td>580026</td>
</tr>
<tr>
<td>Color Display</td>
<td>570013</td>
</tr>
<tr>
<td>Recorder</td>
<td>380004</td>
</tr>
<tr>
<td>Rubber Feet</td>
<td>680010</td>
</tr>
<tr>
<td>Pneumatic Hose for NIBP</td>
<td>560000</td>
</tr>
<tr>
<td>Window</td>
<td>2457-00-13</td>
</tr>
<tr>
<td>Speaker Assembly</td>
<td>2616-00-10</td>
</tr>
<tr>
<td>Fan Assembly</td>
<td>2620-00-10</td>
</tr>
<tr>
<td>Rear Enclosure (Rear bezel)</td>
<td>2566-00-11</td>
</tr>
<tr>
<td>Front Bezel</td>
<td>2565-00-11</td>
</tr>
<tr>
<td>Handle</td>
<td>2570-00-11</td>
</tr>
</tbody>
</table>

### Fuses

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

<table>
<thead>
<tr>
<th>Part</th>
<th>Description</th>
<th>Ivy Part Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power Entry Module (2)</td>
<td>1.6ASB, 5x20mm</td>
<td>290021</td>
</tr>
<tr>
<td>Mother Board – F1</td>
<td>5ASB, ASSY, SMT.</td>
<td>290503</td>
</tr>
<tr>
<td>Mother Board – F2, F3 &amp; F4</td>
<td>3/8ASB, ASSY, SMT</td>
<td>290502</td>
</tr>
</tbody>
</table>
## Cables and Harnesses

<table>
<thead>
<tr>
<th>Part</th>
<th>Ivy Part Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Masimo Internal Sp02 Cable</td>
<td>2451-01-01</td>
</tr>
<tr>
<td>Andros Internal EtCO2 Cable</td>
<td>2317-01-01</td>
</tr>
<tr>
<td>EtCO2 Signal Power Supply Harness Assembly</td>
<td>2335-00-01</td>
</tr>
<tr>
<td>EtCO2 Signal Interface Harness Assembly</td>
<td>2336-00-01</td>
</tr>
<tr>
<td>Backlight Inverter</td>
<td>2470-01-10</td>
</tr>
<tr>
<td>NIBP Interface Ribbon</td>
<td>2609-00-10</td>
</tr>
<tr>
<td>Recorder Interface Ribbon</td>
<td>2608-00-10</td>
</tr>
<tr>
<td>COM 1 &amp; COM 2 Interface Ribbon</td>
<td>2614-00-10</td>
</tr>
<tr>
<td>Telemetry Interface Ribbon</td>
<td>2611-00-10</td>
</tr>
<tr>
<td>Power Supply Input</td>
<td>2612-00-01</td>
</tr>
<tr>
<td>Power Entry Module</td>
<td>2613-00-01</td>
</tr>
<tr>
<td>Display Interface Ribbon</td>
<td>2615-00-10</td>
</tr>
<tr>
<td>Analog Output Interface Ribbon</td>
<td>2619-00-10</td>
</tr>
<tr>
<td>Horizontal Front Panel</td>
<td>2605-00-10</td>
</tr>
<tr>
<td>Vertical Front Panel</td>
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<tr>
<td>Harness Interface Ribbon</td>
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## Labels

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<tr>
<th>Part</th>
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<tr>
<td>Front Panel Label, Vertical</td>
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<tr>
<td>Front Panel Label, Horizontal</td>
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<tr>
<td>Ivy Model Number Label (Masimo)</td>
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<tr>
<td>Rear Panel Label</td>
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<tr>
<td>Input Connector Label (ECG/Resp, NIBP, Sp02, 2Temp, 2Press, EtCO2)</td>
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<td>Input Connector Label (ECG/Resp, NIBP, Sp02, 2 Press)</td>
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<td>Input Connector Label (ECG/Resp, NIBP, Sp02)</td>
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## Software

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<td>450C Program (1 of 2)</td>
<td>2600-00-04</td>
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<tr>
<td>Mother Board – U53</td>
<td>450C Program (2 of 2)</td>
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<td>Mother Board – U26</td>
<td>DSP software</td>
<td>2636-00-04</td>
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<tr>
<td>Mother Board – U98</td>
<td>450C Video</td>
<td>2634-00-04</td>
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</tbody>
</table>
**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 described 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.

EtCO₂ 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.

EtCO₂ 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 SpO₂ 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 SpO2 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.
DISASSEMBLY AND ASSEMBLY

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
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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ISOLATED

NON-ISOLATED

NOTES:
1. ALL RESISTORS ARE 1/4W, 1% U.O.S.
2. LAST USED:
3. NOT USED:
NOTES:
1. LAST USED: C230, D44, DS6, E7, F4, FB5, J24,
   J25, J26, J28, J99, J100, J101, J102, J103,
   J111, J112, J113, J114, J115, J116,
   J117, J118, J119, J120, J121,
   J122, J123, J124, J125, J126,
   J127, J128, J129, J130, J131,
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   J468, J469, J470, J471,
SPECIAL FOR ACCOMMODATING PATIENT CABLES WITH 1K SERIES RESISTORS.
OPTIONAL

THIS CIRCUITRY IS FOR THE ETHERNET OPTION
REVOLUTION HISTORY REV-00 THRU REV-17
REFER TO ECN 1274 IN THE ENGINEERING RECORD FILES.

REVISED PER ECN 1274.
REF: APR: 6-11-03

REVISED PER ECN 1289.
REF: APR: 6-25-03

REVISED PER ECN 1290.
REF: APR: 5-27-05

REVISED PER ECN 1326.
REF: APR: 6-25-03

REVISED PER ECN 1354.
REF: APR: 4-13-04

REVISED PER ECN 1432.
REF: APR: 5-27-05

NOTES:
1. LAST USED: C230, D44, DS6, E7, F4, FB5, J24,
3. ALL RESISTORS ARE 1/10W, SIZE 0805 UNLESS
   OTHERWISE SPECIFIED.

IVY BIOMEDICAL SYSTEMS INC.
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BRANFORD, CT., 06405 USA
(203) 481-4183

MARK TUCCELLO 9/5/01
CHK: GP 9/5/01
APR: RAM 9/5/01

BYPASS

A 5143-00-01 (-03 SCHEMATIC)

Date: Friday, May 27, 2005
1. ALL RESISTORS ARE 1/4W, 1% U.O.S.

NOTES:

2. LAST USED:

3. NOT USED: