TidalGuard™ Sp
Capnograph/Pulse Oximeter

SHARN VETERINARY, INC.

HANDHELD CAPNOGRAPH/OXIMETER

User's Manual

Model TidalGuard™

August 18, 2006
Catalog No. 1027688-B

Sharn Veterinary
12706 Casey Road
Tampa, FL 33618

Revision History

10-Aug-05 Release, Rev. A, CO_N2391
18-Aug-06 Rev. B, CO_N3229

Declaration of Conformity with European Union Directive

The Authorized Representative for this equipment is:

Respironics Deutschland
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CE
0086

Guarantee

Equipment manufactured or distributed by Respironics, Inc. is fully guaranteed, covering materials and workmanship, for a period of one year from the date of shipment, except for certain disposable products and products with stated guarantees other than one year. Respironics reserves the right to perform guarantee service(s) at its factory, at an authorized repair station, or at the customer's installation.

Respironics' obligations under this guarantee are limited to repairs, or at Respironics' option, replacement of any defective parts of our equipment, except fuses, batteries, and calibration gasses, without charge, if said defects occur during normal service.

Claims for damages during shipment must be filed promptly with the transportation company. All correspondence concerning the equipment must specify both the model name and number, and the serial number as it appears on the equipment.

Improper use, mishandling, tampering with, or operation of the equipment without following specific operating instructions will void this guarantee and release Respironics from any further guarantee obligations.

Customer Service & Product Support:

USA and Canada
Phone 1-800-345-6443
Customer Service Fax 1-800-886-0245
Product Support Fax 1-724-387-5236

International
Phone 724-387-4000
Fax 724-387-5012

service@respironics.com
clinical@respironics.com
www.respironics.com

Caution: Federal (U.S.A.) law restricts this device to sale, distribution, or use by or on the order of a licensed medical practitioner.

Service Policy

The Respironics Hospital Services Group provides depot service for monitors and 24-hour a day access to technical support through its Technical Support Department in Murrysville, PA. (Outside the U.S., primary technical support is handled through our qualified international sales and service distributors.)

Contact the Technical Support Department by telephone toll free at 800-345-6443 ext 5; by facsimile at 724-387-5236; or by e-mail at service@respironics.com for technical inquiries or clinical@respironics.com for clinical inquiries After hours telephone support requests (before 8:00 AM and after 5:00 PM Eastern Time) will be responded to promptly by the Technical Support on-call staff. After hours facsimile and e-mail requests will be answered the next business day. It is suggested that any person calling in for technical support have the equipment available for product identification and preliminary troubleshooting.

Respironics reserves the right to repair or replace any product found to be defective during the warranty period. Repair may be provided in the form of replacement exchange parts or accessories, on-site technical repair assistance or complete system exchanges. Repairs provided due to product abuse or misuse will be considered "non-warranty" and invoiced at the prevailing service rate. Exchanged materials are expected to be returned to Respironics within 10 days for full credit. Return materials should be cleaned as necessary and sent directly to Respironics referencing the RA number provided. (Transferring return materials to a local sales or dealer representatives does not absolve you of your return responsibility.).

If the customer requires the return of their original product, the exchange material will be considered “loaner material” and exchanged again after the customer equipment is repaired.

Please contact Technical Support for information on these additional programs and services:

- Technical & Clinical Training
- Test Equipment and Test Kits
- Service Contract / Parts Insurance Plans
- On-Site Service Support

Trademarks and Patents

CAPNOSTAT is a registered trademark and *TidalGuard*™, Y-Sensor, SuperBright and OxySnap are trademarks of Respironics, Inc. Velcro is a registered trademark of Velcro USA, Inc. Cidex is a trademark of Arbook, Inc. Nafion is a registered trademark of Dow Corning Corp.

The *TidalGuard® Sp* monitor and its sensors and accessories are covered by the following US patents: 4,859,858, 4,859,859, 4,914,720, 5,146,092, 5,153,436, 5,190,038, 5,206,511, 5,251,121, 5,369,277, 5,398,680, 5,448,991, 5,616,923, 5,693,944, 5,793,044, 5,820,550, 5,891,026, 5,999,834. Other patents pending.

Contents

Section 1 General Description

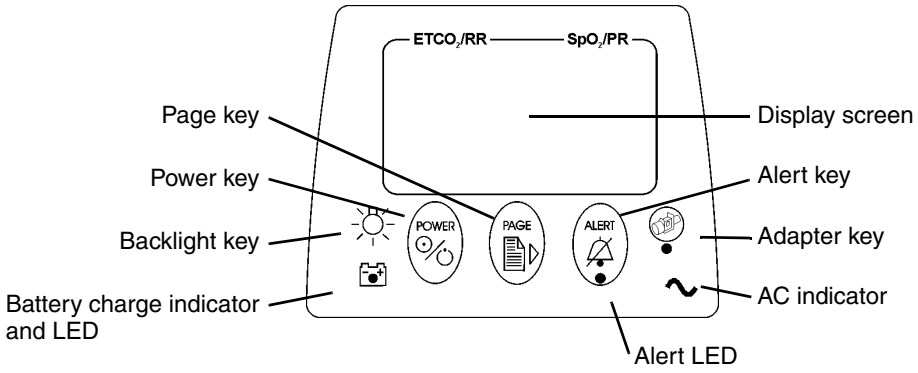
Indication for use

The *TidalGuard™ Sp* handheld, portable Capnograph/Oximeter are intended to be used for monitoring end tidal CO_2, respiration rate, functional oxygen saturation and pulse rate in monitoring environments such as ventilatory support, emergency and anesthesia. *TidalGuard™ Sp* is designed to monitor veterinary patients. *TidalGuard™ Sp* is not intended for any other purpose.

NOTE

Components of this product and its associated accessories which have patient contact are free of latex.

Keypanel Controls and Indicators



Controls

Power Key

Switches power on/off. Press the POWER key to place the unit into operate mode (ON) or to turn the unit OFF. Refer to “AC/Battery Operation” on page 9.

With monitor ON, press and hold the POWER key to enter the MONITORING MODE selection menu. Refer to “Monitoring Mode” on page 27 for more information.

Page Key

Press to set display screen to Data Display, $EtCO_2$ waveform, plethysmogram, $EtCO_2$ trend, Respiration trend or SpO_2 trend.

Alert Key

Press to suspend audible alerts for 2 minutes and display the SET ALERTS menu. If the SET ALERTS menu is not needed, it will automatically disappear after 3 seconds.

For 2 minute suspend, the icon will illuminate for the duration. Press again to cancel.

Press and hold for 3 seconds to disable audible alerts, and the icon will flash. Press and hold again to cancel.

The Alert Key LED will display the following:

- Steady yellow: audio suspended for 2 min., no alert in progress.
- Flashing yellow: audio silenced (no alert in progress).
- Flashing red and yellow: alert in progress; audio is off or 2 minute suspend.

Audible alerts may be permanently disabled from the Configuration menu. Refer to “Configuration Menus” on page 16 for more information.

Adapter Key

Press to set adapter type: regular (adult) or exotic (neonatal).

Press and hold for 4 seconds to zero an adapter. See “Adapter Zero Procedure” on page 22 for more information.

Press to cancel Auto Power Off function.

Backlight Key

Press to turn backlight on/off, or press and hold to adjust contrast for up/down viewing angles and for adjustment due to extreme temperature variations.

Indicators

Battery Alert Indicator

Illuminates when the unit is on battery power. Green; battery is fully charged, slow flashing yellow; battery power is low (approximately 20 minutes of operation remains), Fast flashing red; battery is exhausted (approximately 5 minutes of operation remains). The battery alert indicator is off when external power is connected. Refer to “AC/Battery Operation” on page 9 for information on connecting AC power and charging the battery.

AC Power Indicator

Illuminated green when the monitor is connected to an AC power source (e.g. the external power supply (PN 9220-10), or the BaseStation (PN 6998-00), while powered by the external power supply).

Icons

The icons listed below may appear on the display screen when the *TidalGuard™ Sp* is in use.

Alert Silence Icon

Audible alerts silenced.

2-Minute Suspend Icon

Audible alert suspended for two minutes.

Alert Limits Disabled Icon

Alert limits disabled. Select ENABLED or DISABLED in the CONFIGURATION menu.

Airway Adapter Icon

Indicates adapter key.

Time/Date Icon

Set time/date. Press from the CONFIGURATION menu to set time and date.

Backlight Icon

Indicates backlight key.

Trend Screen Icon

Displayed beside any Trend screen.

Temperature Icon

Sensor not up to temperature icon. Displayed when performing an adapter zero and the sensor is not at operating temperature.

Waveform Icon

CO_2 detected icon. Displayed when selecting an adapter zero and the monitor detects breaths.

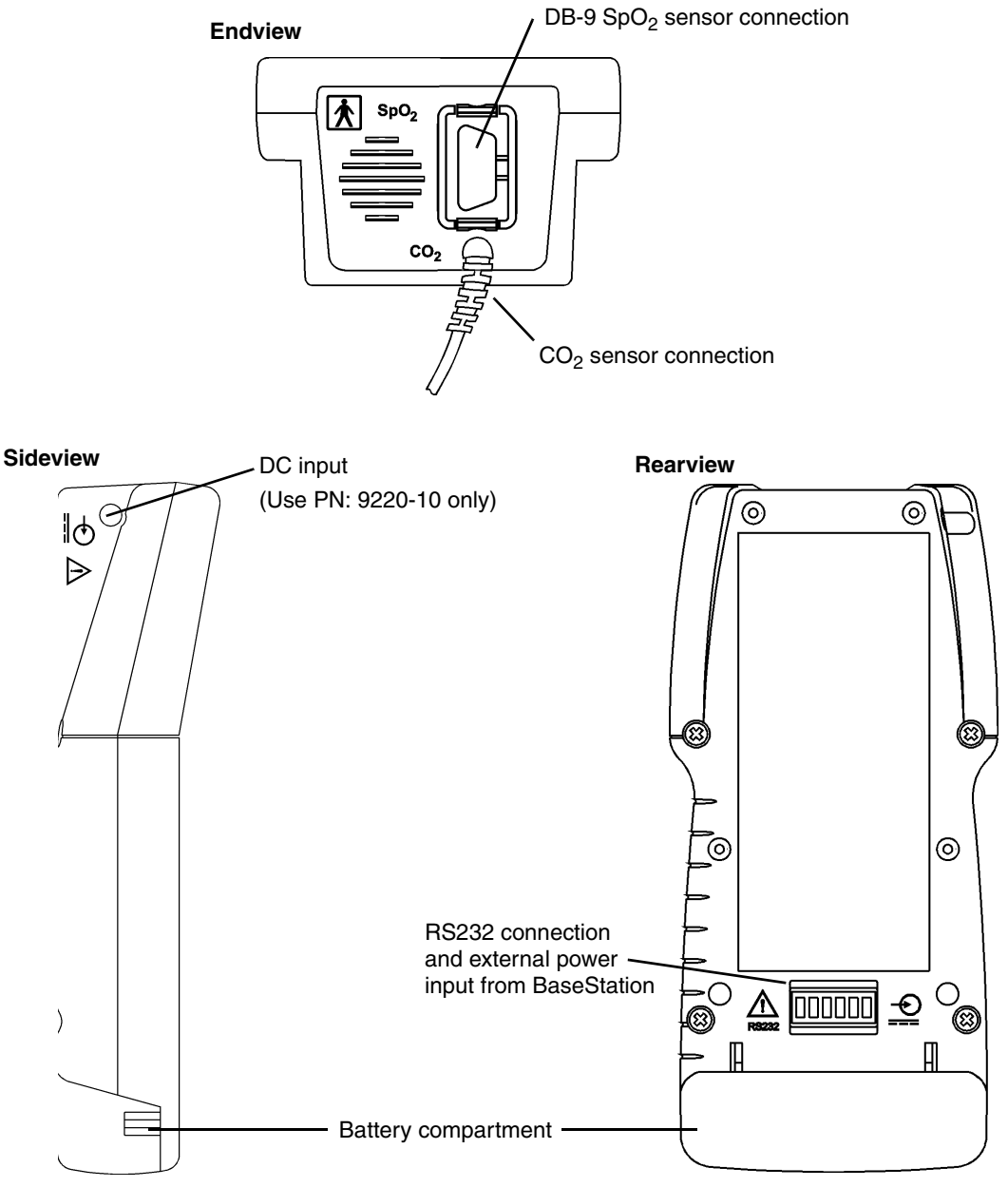
Heart Icon

Pulse detected icon. Displayed when SpO_2 sensor is attached to patient and the monitor detects a pulse.

Lung Icon

Breaths detected icon. Displayed when CAPNOSTAT® CO_2 sensor is attached to patient and breaths are detected.

Connections and Labeling



Symbols

Patient isolation: Identifies connection as type BF

Attention: Consult manual for detailed information

DC input. Connect external power supply to this port. Use only an approved external power supply, Catalogue number 9220-10.

Recyclable item. This symbol is found on the internal battery and should not concern the common user. Refer to qualified service personnel when battery replacement is required.

Compliant with the WEEE/RoHS recycling directives.

Separate collection. Appropriate steps must be taken to ensure that spent batteries are collected separately when disposed of.

Principle of operation

CO_2

TidalGuard™ Sp uses the CAPNOSTAT® CO_2 sensor to measure CO_2 by using the infrared absorbtion technique, which has endured and evolved in the clinical setting for over two decades and remains the most popular and versatile technique today.

The principle is based on the fact that CO_2 molecules absorb infrared (IR) light energy of specific wavelengths, with the amount of energy absorbed being directly related to the CO_2 concentration. When an IR beam is passed through a gas sample containing CO_2, the electronic signal from the photodetector (which measures the remaining light energy) can be obtained. This signal is then compared to the energy of the IR source and calibrated to accurately reflect CO_2 concentration in the sample. To calibrate, the photodetector's response to a known concentration of CO_2 is stored at the factory in the monitor's memory. A reference channel accounts for optical changes in the sensor, allowing the system to remain in calibration without user intervention.

SpO_2

The *TidalGuard™ Sp* determines oxygen saturation using sensors that contain red and infrared (660 and 940 nanometer) light sources, called light emitting diodes (LEDs). The light energy from each LED is beamed through a tissue sample—a pulsating vascular bed such as the patient's tongue. The remaining light energy not absorbed by the tissue sample reaches a photodiode light receptor in the sensor. Oxygen saturated blood absorbs different amounts of light at each wavelength as compared to desaturated blood. Therefore, the amount of light absorbed by the blood in each pulse can be used to calculate oxygen saturation.

The *TidalGuard™ Sp* is calibrated to display "functional" saturation. This differs from the "fractional" saturation value displayed by most co-oximeters. Functional saturation is defined as:

$$\text{Functional Saturation} = \frac{HbO_2}{100 - (COHb + METHb)}$$

HbO_2 = Fractional Oxyhemoglobin
COHb = Carboxyhemoglobin
METHb = Methemoglobin

This can be considered to represent the amount of oxyhemoglobin as a percentage of the hemoglobin that can be oxygenated. Dysfunctional hemoglobins (COHb and METHb) are not included in the measurement of functional saturation.

Pulse Rate is calculated by measuring the time interval between peaks of the infrared light waveform. The inverse of this measurement is displayed as pulse rate.

The oxygen saturation and pulse rate values are updated once each second. Presence of a pulse is indicated visibly by a plethysmogram graphic display and audibly by a "beep," when configured.

The *TidalGuard™ Sp* must be used in conjunction with SuperBright™ Sensors.

Section 2 *Safety*

For maximum patient and operator safety, you must follow the following warnings and cautions.

WARNINGS
Indicates a potentially harmful condition that can lead to personal injury.

- **Explosion Hazard:** *DO NOT* use *TidalGuard™ Sp* in the presence of flammable anesthetics. Use of this instrument in such an environment may present an explosion hazard.
- **Electrical Shock Hazard:** Always turn *TidalGuard™ Sp* off and remove any external devices before cleaning it. Refer servicing to qualified service personnel.
- **Failure of Operation:** If the monitor fails to respond as described, do not use it until the situation has been corrected by qualified personnel.
- Do not operate *TidalGuard™ Sp* if it appears to have been dropped or damaged.
- Do not operate *TidalGuard™ Sp* or its accessories when it is wet due to spills or condensation.
- Never sterilize or immerse the monitor, sensor or accessories in liquids.
- The monitor does not alert for NO RESPIRATION if the airway adapter is removed from the CAPNOSTAT® CO_2 sensor.
- Verify the "No Resp Timer" setting prior to use.
- Do not position any sensor cable in a way that may cause entanglement or strangulation.
- The *TidalGuard™ Sp* is not intended to be used as a primary diagnostic apnea monitor and/or recording device.
- Patient Safety: Care should be exercised to assure continued peripheral perfusion distal to the SpO_2 sensor site after application.
- Inspect the SpO_2 sensor site often for adequate circulation - at least once every four hours. When applying sensors take note of patient's physiological condition. For example, burn patients may exhibit more sensitivity to heat and pressure and therefore additional consideration such as more frequent site checks may be appropriate.
- Data Validity: As with all pulse oximeters, inaccurate SpO_2 and Pulse Rate values may be caused by:
  - Incorrect application or use of sensor;
  - Significant levels of dysfunctional hemoglobin; carboxyhemoglobin or methemoglobin;
  - Significant levels of indocyanine green, methylene blue, or other intravascular dyes;
  - Exposure to excessive illumination such as surgical lamps-especially those with a xenon light source, or direct sunlight;
  - Excessive patient movement;
  - Venous pulsations;
  - Electrosurgical interference.
- The external battery charger should NOT be used to recharge the battery near or in close proximity to patients and/or other medical equipment in operation. It is intended for use in service areas only (i.e. nurses station, biomed lab, etc.).

- Connection of an external device (e.g. printer or computer) to the RS232 serial port on the BaseStation may compromise patient safety.
- Use of the *TidalGuard™ Sp* monitor is restricted to one patient at a time. Do not connect the sensors to multiple patients simultaneously.
- The *TidalGuard™ Sp* monitor provides no protection against the effects of a defibrillator. The patient sensors must not be located between defibrillator pads when a defibrillator is used on a patient.
- To reduce the hazard of burns in the high-frequency surgical neutral electrode connection, the patient sensors should not be located between the surgical site and the electro-surgical unit return electrode.
- The use of accessories, sensors and cables other than those specified by Respironics may increase emissions or decrease immunity of the equipment.
- The use of portable and mobile radio frequency (RF) communications equipment can affect this and other pieces of medical equipment.

CAUTIONS
Indicates a condition that may lead to equipment damage or malfunction.

- Caution: Federal (U.S.A.) law restricts this device to sale, distribution, or use by or on the order of a licensed medical practitioner.
- Use only an approved external power supply with this device. Use of any other power supply may damage the *TidalGuard™ Sp* and void the warranty.
- Do not operate *TidalGuard™ Sp* or its accessories when it is wet due to spills or condensation.
- Do not operate *TidalGuard™ Sp* if it appears to have been dropped or damaged.
- Keep *TidalGuard™ Sp* and its accessories clean.
- Inspect the integrity of the *TidalGuard™ Sp* and its accessories prior to use.
- Never sterilize or immerse the monitor, sensor or accessories in liquids.
- Do not sterilize or immerse sensors except as directed in this manual.
- Do not apply excessive tension to sensor cable.
- Do not store the monitor or sensors at temperatures less than 14°F (-10°C) or above 131°F (55°C).
- Do not operate the monitor or sensors at temperatures below 50°F (10°C) or above 104°F (40°C).
- If an adapter leaks or becomes occluded, replace and discard the occluded adapter.
- It is recommended that the CAPNOSTAT® CO_2 sensor be removed from the circuit whenever an aerosolized medication is delivered. This is due to the increased viscosity of the medications which may contaminate the sensor windows, causing the sensor to fail prematurely.
- Where electromagnetic devices (i.e. electrocautery) are used, patient monitoring may be interrupted due to electromagnetic interference. Electromagnetic fields up to 3V/m will not adversely affect system performance.
- Refer servicing to qualified personnel.
- Use only approved sensors and accessories with the *TidalGuard™ Sp* monitor.
- Observe precautions for electrostatic discharge (ESD) and electromagnetic interference (EMI) to and from other equipment.
- Where electromagnetic devices (i.e., electrocautery) are used, patient monitoring may be interrupted due to electromagnetic interference. Electromagnetic fields up to 3 V/m will not adversely affect system performance.

- Sudden erratic changes in the CO_2 and pressure waveforms that do not correlate to the physiological condition of the patient may be signs that the monitor is experiencing electromagnetic interference.
- The *TidalGuard™ Sp* monitor should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.
- The *TidalGuard™ Sp* monitor complies with IEC 60601-1-2:2001, providing reasonable protection against electromagnetic interference in a typical medical installation. The equipment generates, uses and can radiate electromagnetic interference (EMI), and if not installed and used in accordance with the instructions, may cause interference with other devices in the vicinity.

  If interference does occur, correct it using one or more of the following measures:
  - Move the receiving device or increase separation between the equipment.
  - Consult Respironics or members of the hospital's engineering department for more information.
- The *TidalGuard™ Sp* monitor is not intended for use in a hyperbaric chamber or an MRI (Magnetic Resonance Imaging) environment

NOTES
Indicates points of particular interest or emphasis for more efficient or convenient operation.

- The *TidalGuard™ Sp* monitor is intended for operation with airway adapters.
- Operating the *TidalGuard™ Sp* below 50°F (10°C) will result in longer warm-up time and reduce battery life.
- Components of this product and its associated accessories which have patient contact are free of latex.
- Certain rebreathing circuits, or the presence of artifacts such as cardiogenic oscillations, may cause *TidalGuard™ Sp* to react to non-respiratory CO_2 fluctuations as if they were breaths. This condition affects the RESP numerical displays and may also affect the $ETCO_2$ display when using single breath averaging; the capnogram display continues to provide an accurate picture of the CO_2 waveform.
- After the life cycle of our equipment and all accessories has been met, disposal of the equipment should be accomplished following the national requirements. Contact the local customer service representative for questions concerning disposal.
- Accessories equipment connected to the analog and digital interfaces must be certified to the respective IEC standards: IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment. Furthermore, all configurations shall comply with the system standard IEC 60601-1-1.

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Section 3 Preparation for Use

The *TidalGuard™ Sp* can be powered four ways: from seven "AA" disposable lithium batteries, a rechargeable DR30 NiMH battery, the 9220-10 external power supply or a 6998-00 BaseStation combined with the external power supply.

AC/Battery Operation

Press the POWER key to place the unit into operate mode (ON) or to turn the unit OFF. The status of the unit is dependent upon both the Power key and the power source.

The monitor can operate for up to 4.5 hours while powered from a fully charged internal battery. The battery is charging when the monitor is powered through its DC input and the keypanel icon is green. The battery will charge even if the monitor is off. Power to the DC input is supplied by the external power supply (Cat. No. 9220-10) with or without the optional BaseStation (Cat. No. 6998-00).

Rechargeable and disposable battery capacity is shown in the table titled, "Battery Life and Recharge Times" on page 14. Times may be reduced in colder temperatures; operation with the backlight off may slightly increase these times.

Battery Status and Alerts

When the monitor is operating on battery power, and the battery is sufficiently charged, the battery icon LED on the keypanel will be green. The battery level is reflected on the battery icon by different colors (for example, battery fully charged: green, battery low: flashing yellow).

The LED on the keypanel flashes red when the monitor is powered by its internal battery and approximately 5 minutes remain. The monitor will sound an audible alert, then when the battery is depleted, turn itself off. This alert can only be silenced by connecting the external supply or turning the monitor off. The NiMH battery pack should be replaced, or the *TidalGuard™ Sp* BaseStation (Cat. No. 6998-00) or external power supply (Cat. No. 9220-10) should be connected to recharge the battery (rechargeable batteries only) and power the monitor. See "Battery Life and Recharge Times" on page 14.

NOTE

When the battery is low (red blinking battery LED on keypanel) the monitor has shut down CO_2 and SpO_2 functions. Connect to AC power as soon as possible.

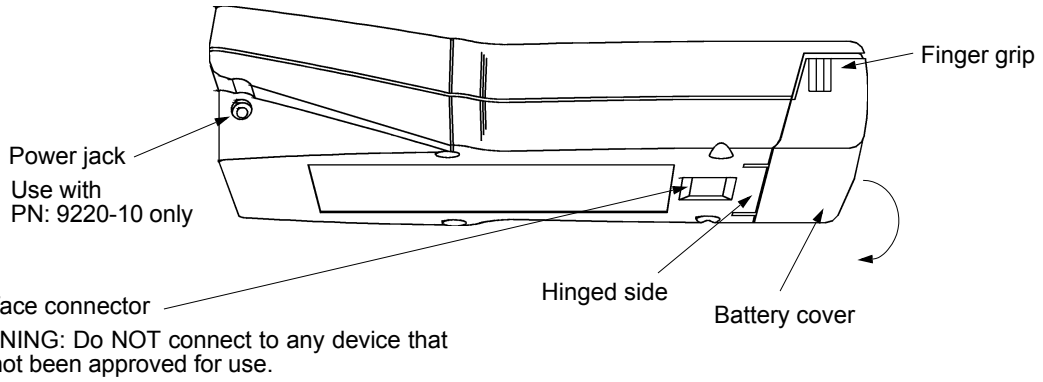
NOTE

- The battery life indicator may not reflect the true battery status upon power-up for approximately 30 seconds.
- The battery life indicator is inactive when the monitor is powered by the BaseStation or the external power supply.

Battery Use and Options

Removing and Installing the Battery

Grasp the finger grips on each end of the battery cover. Squeeze together and pull so that the cover opens to reveal the internal battery (the cover is hinged on the bottom of the case). Remove the battery from the monitor.



The battery is keyed so that it can be installed in only one way (see illustration inside battery compartment). The contacts should go in first and be located toward the top left of the monitor when inserting. Make certain the battery cover is properly closed before operating the monitor.

Rechargeable Batteries

The DR30 NiMH rechargeable battery pack (Cat. No. 400043) can be used to power the *TidalGuard™ Sp* for approximately 4.5 hours of continuous operation.

Optional DR30
Rechargeable battery,
(NiMH 7.2 vdc)

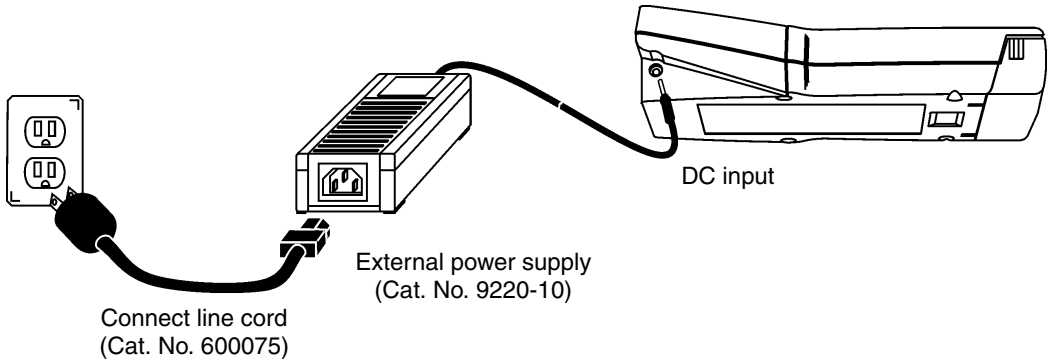
NOTE

- Refer to the instruction sheet packaged with the rechargeable battery for complete operating instructions.

To charge a rechargeable battery while in the monitor:

External Power Supply

Alternatively, plug the external power supply directly into the DC power jack on the side of the monitor, and connect a hospital-grade line cord to an AC source. The AC icon ∿ will illuminate green and the battery will charge in approximately 5.5 hours. If the monitor has been stored with the battery installed for thirty (30) days or more, charge the battery for 24 hours prior to use.



CAUTION

- Use only approved devices when connecting to the power input jacks on the *TidalGuard™ Sp* or on the BaseStation.
- Do not attempt to use the adapter for the external battery charger for this function.

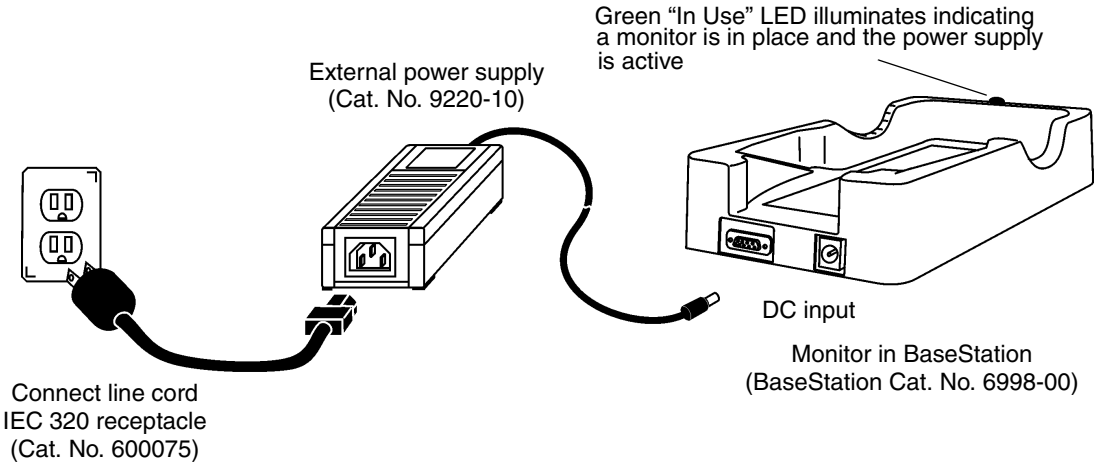
NOTE

- When powered by the external power supply, the *TidalGuard™ Sp* will not overcharge a rechargeable battery.
- The external power supply has a universal power input. The IEC 320 input receptacle for line cord connection allows compatibility with every country's voltage and frequency requirements.

Optional BaseStation

Power for the BaseStation is supplied by an external power supply (PN 9220-10) or the internal battery. When the power supply is properly connected to the BaseStation and a monitor is placed within the station the green, "In Use" LED will illuminate. The ∿ icon on the monitor will also illuminate indicating that external power is connected.

Connect the external power supply jack to the monitor and connect a hospital-grade line cord from the external power supply to an AC source.



The 9220-10 Power Supply is approved by the following regulatory agencies:

: Canadian Standards Assoc. : VDE (Germany) : DEMKO (Denmark)

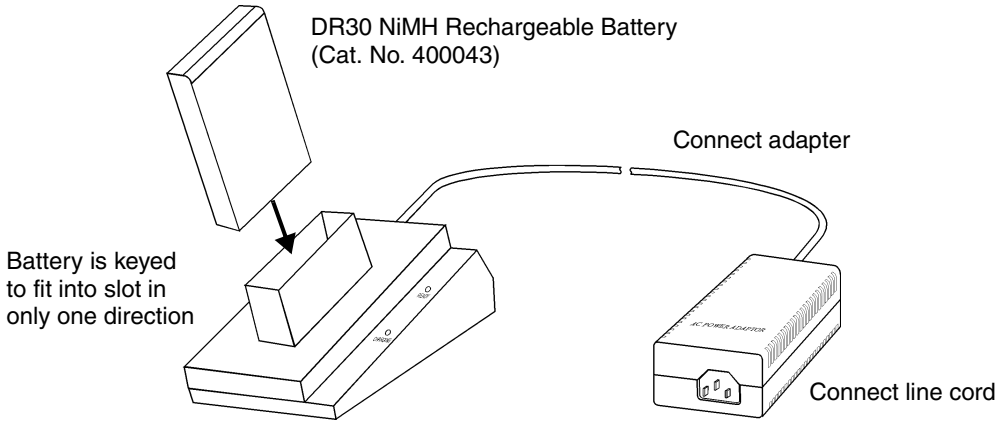
: SEMKO (Sweden) : FINKO (Finland)

CAUTION

- Although other connectors may physically fit, do not attempt to connect any device other than power supplies that have been approved for use with this device. Doing so may damage the *TidalGuard™ Sp* and will void the warranty.
- Never sterilize or immerse the monitor, sensor or accessories in liquids.

Charging NiMH Rechargeable Battery with External Charger

In a non-patient area, connect the adapter to an AC source, then plug the adapter jack into the charger. Remove the battery from the *TidalGuard™ Sp* and insert it into the external charger. The battery will be fully charged in approximately 4.5 hours. The external charger is for use with the DR30 NiMH rechargeable battery pack (Cat. No. 400043) only. Refer to the instructions supplied with the charger for additional information.



WARNING

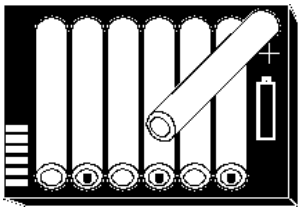
- The external battery charger should NOT be used to recharge the battery near or in close proximity to patients and/or other medical equipment in operation. It is intended for use in service areas only (i.e. nurses station, biomed lab, etc.).

NOTE

- With a new battery, or a battery that has not been used for 30 days or more, charge the battery for 24 hours prior to use.
- When powered by the external power supply or the BaseStation, the *TidalGuard™ Sp* will not overcharge a rechargeable battery.
- The monitor may not operate on battery power if the battery is not sufficiently charged.
- Dispose of batteries in accordance with local laws.

AA Lithium Batteries

To power *TidalGuard™ Sp* from AA lithium batteries, insert seven disposable batteries (Energizer L91 or equivalent) into the optional Battery Case (Cat. No. 6862-00) following the polarity markings on the Battery Case.



Standard
AA lithium batteries
(7 ea. - disposable)

WARNING

- Batteries can explode, leak or catch on fire if heated or exposed to fire or high temperatures.
- Do not mix battery types (e.g. disposable and rechargeable AA batteries).

Battery Life and Recharge Times

Configuring the monitor to turn off unused functions will result in longer battery life. The following table lists battery operation times (see "Monitoring Mode" on page 27).

Configuration	Power source - Approximate Monitoring Times	
	Rechargeable NiMH battery	AA lithium batteries
CO_2/SpO_2	4.5 hours	4.0 hours
CO_2 only	4.5 hours	4.0 hours
SpO_2 only	7.0 hours	6.5 hours
Recharge Time: External charger w/adapter	4.5 hours	n/a
Recharge Time: External power supply or External power supply/BaseStation	5.5 hours (in monitor)	n/a

NOTE

Excessive alerting reduces battery life when operating on battery power.

Automatic Power Off Feature

The automatic power off feature is included to conserve battery power in the event of an unintentional power up of the monitor. This option will shut the monitor off if there is no CO_2 breath or pulse detection after 5 minutes from when the unit powers on, or after 20 minutes of no monitoring (no breath or pulse detected and no alert conditions). After the 5 or 20 minutes has elapsed, an AUTO POWER OFF IN X:XX message will appear on the screen and the timer (X:XX) will count down from one minute to zero. Pressing the adapter key, or detection of a CO_2 breath or pulse will cancel the shutdown, otherwise the unit will shut off.

Long Term Storage

If the monitor has not been used or powered by the external power supply for an extended time* (3 months or more) allow the battery to charge before use or replace the battery with a fully charged battery and continue monitoring. The monitor may not power up on battery power if the battery is not sufficiently charged. Refer to "Battery Life and Recharge Times" on page 14.

NOTE

- New batteries, or batteries stored for extended periods of time may need to be fully charged and discharged up to five (5) times before performing at full capacity.
- With a new battery, or a battery that has not been used for 30 days, charge the battery for 24 hours prior to use.

Serial Communications/Power Interface Connector

Located on the enclosure rear is a six pin modular contact which provides an RS232 interface as well as a power input for unit operation and battery charging when connected to approved accessories. This connector meets the patient safety requirements of the following agency: IEC 60601-1.

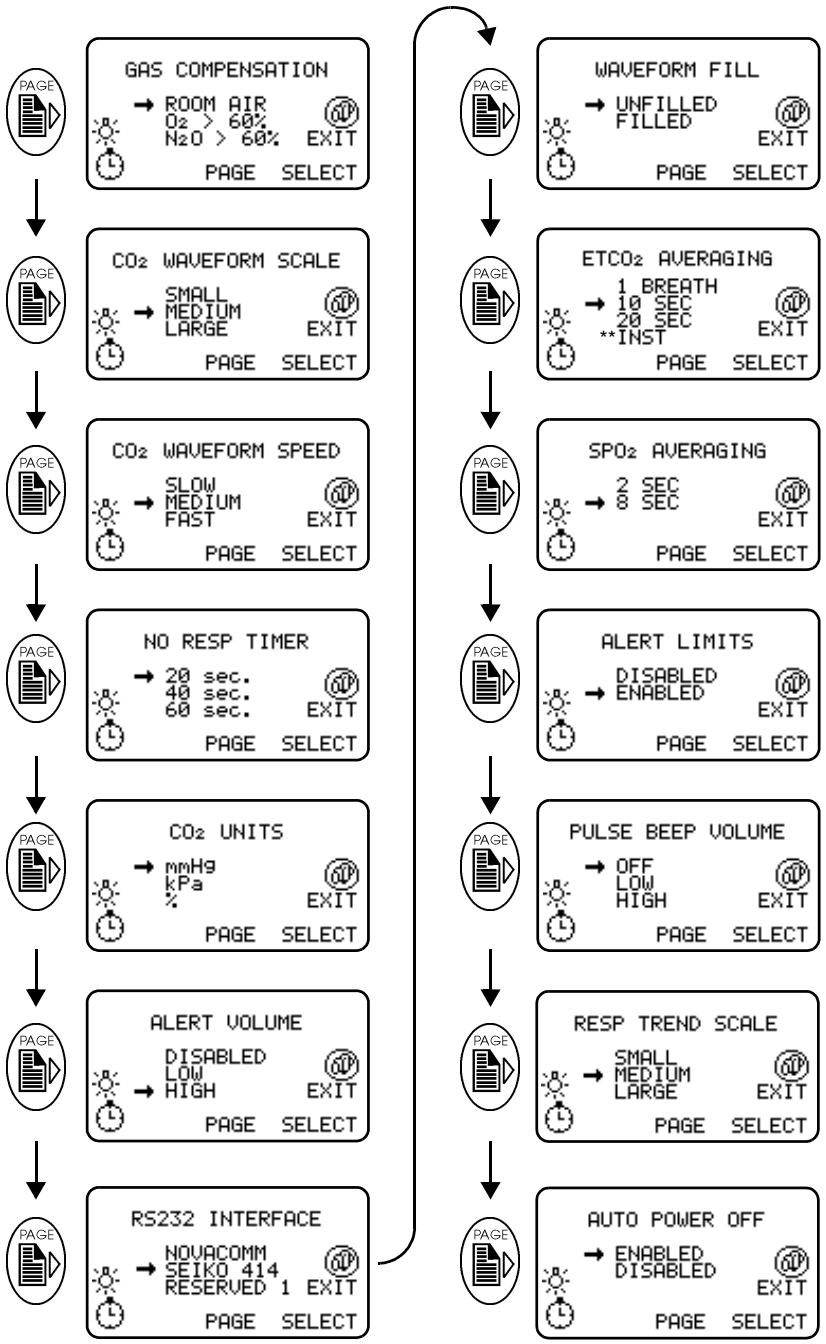
The BaseStation is an optional accessory onto which hand-held monitors can be placed, providing a platform for communication support between the monitor and a host computer. The BaseStation is meant for table-top (horizontal), *not* pole-mounted (vertical) applications and can be used anywhere the *TidalGuard™ Sp* monitor is used; including but not limited to the sleep lab, ICU, anesthesia, post anesthesia, emergency department, respiratory care, home care, and pre-hospital emergency.

The BaseStation provides RS232 serial communications as supported by the monitor, with or without the external power supply connected. In addition, the BaseStation is capable of providing power to charge a rechargeable battery inside the monitor when used with the external power supply.

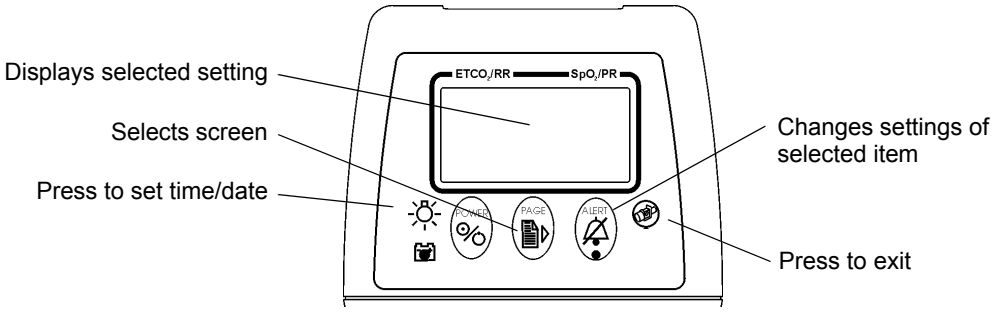
*The internal battery will slowly discharge over long periods of non-use.

Configuration Menus

CONFIGURATION menus are provided on the *TidalGuard™ Sp* to allow customizing of various settings. To access the CONFIGURATION menus, press and hold the key, then simultaneously press the key until the first CONFIGURATION menu is displayed. Press the PAGE key to move through the menus. The SELECT key moves the arrow pointer; the parameter chosen will flash. Press the EXIT key at any time to return to monitoring mode (selections will be saved).



**Press SELECT to scroll down to INST in the $EtCO_2$ Averaging menu.



NOTE

If an attempt is made to change CO_2 units after data has been collected, a message warning that trend memory will be erased is displayed. To change units and erase trends, press the OK key to continue, then the EXIT key to confirm and exit.

Configuration Settings

The CONFIGURATION menus can be programmed by the user to customize the *TidalGuard™ Sp*. Any changes made will be retained when the monitor is turned off. NOTE: To reset the monitor to its factory default settings: with the monitor off, press and **hold** the key and the key, then press the key to turn the monitor on.

Options are listed below with descriptions following:

Parameter	Settings and Description	Factory Default
GAS COMPENSATION[A]	Room air, O_2 > 60%, N_2O > 60% Use this setting to enter the gas composition in order to compensate the CO_2 measurement for gas density. Any setting other than the default will cause the monitor to display "O_2" or "O_2 N_2O" on the screen beside the respiration value.	Room Air
CO_2 WAVEFORM SCALE	Small, Medium, Large Select the desired size of the capnogram waveform.	Medium
CO_2 WAVEFORM SPEED	Slow, Fast, Medium Select the desired speed of the capnogram waveform.	Medium
NO RESP TIMER	20 sec., 40 sec., 60 sec. Alert setting activates if the end tidal CO_2 portion of the monitor cannot detect regular breaths for periods longer than 10 seconds.	20 sec.

A. If FiO_2 is less than 60% and N_2O is selected as the balance gas, an incorrect INSP O_2 settings may cause the reported CO_2 value to be overestimated (too high) by up to 11.7% of its reading. If FiO_2 is greater than 60% and N_2 is selected as the balance gas, an incorrect INSP O_2 setting may cause the reported CO_2 value to be underestimated (too low) by up to 6.4% of its reading.

CO_2 UNITS	mmHg, kPa, % Select the desired units for both the capnogram and $ETCO_2$ values. Note that changing the CO_2 units in the Configuration menu will result in a loss of all stored data. The message "WARNING: CHANGING CO2 UNITS ERASES STORED TRENDS" will display. Press CANCEL, or press the OK key to acknowledge the warning, and return to the CO2 UNITS menu. Press the Adapter key to EXIT	mmHg
ALERT VOLUME	Disabled, Low, High Select the desired volume of audible alerts. Note that care should be taken to set the volume level above ambient noise levels.	High
RS232 INTERFACE	NOVACOMM (used when connected to an external PC with optional software), RESERVED 1, and RESERVED 2.	NOVACOMM
WAVEFORM FILL	Unfilled, Filled Select the desired appearance of the capnogram waveform.	Unfilled
$ETCO_2$ AVERAGING	1 Breath, 10 sec, 20 sec, INST Select the interval from which the displayed value of end tidal CO_2 ($ETCO_2$) is calculated.	10 sec
SpO_2 AVERAGING	2 sec, 8 sec Select the interval from which the displayed value of oxygen saturation (SpO_2) is calculated.	8 sec
ALERT LIMITS	Disabled, Enabled Enable or disable the Alert Limits function. Select the desired high and low alert limits by exiting the CONFIGURATION menu and pressing the Alert key.	Disabled
PULSE BEEP VOLUME	Off, Low, High Select the desired volume of pulse beep. Note that care should be taken to set the volume level above ambient noise levels.	OFF
RESP TREND SCALE	Small, Medium, Large Select the desired size of the respiration trend waveform.	Medium
AUTO POWER OFF	Enabled, Disabled Selects automatic shut off of unit if no signal is detected, to conserve battery power.	Enabled

The following parameters are accessed by pressing -☼- from one of the previous Configuration menus. Press -☼- to move through the menus.

SET TIME AND DATE	Press the 24 hour format. Day number, short month name, year (e.g. 14-DEC-1998) (From within the CONFIGURATION Menu, press -☼- key to access this screen). Select to program or change the time and date. The format is "TIME: HH:MM DDmmmYYYY" where HH=hours from 00-23, MM=minutes from 00-59, DD=days of the month from 01-31, mmm=month, YYYY=year (using all four digits).	
LANGUAGE	All languages available in the current software release are listed in this menu.	
SOFTWARE REVISIONS MAIN PROGRAM	Date, time and version of software currently loaded in to this unit.	
CAPNOSTAT SERIAL # VERIFY ACCURACY	Serial number of CAPNOSTAT® CO_2 sensor attached to this monitor. Verifying monitor accuracy with calibration gas should be performed only by qualified service personnel.	

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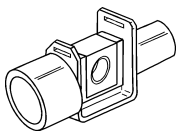
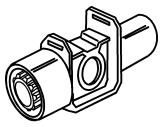
Section 4 *Sensors and Patient Connections*

Adapter Types Available



Regular (Adult) Airway Adapter (Catalog No. 6063):

- For intubated patients with endotracheal tube diameters greater than 4 mm. Adds approximately 5 cc of deadspace;

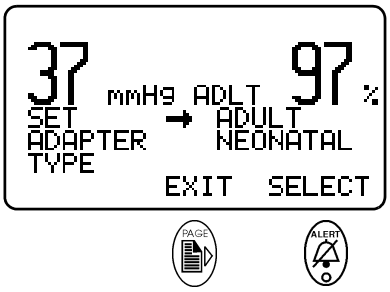


Exotic (Neonatal) Airway Adapter (Catalog No. 6312):

- For intubated patients with endotracheal tube diameters no more than 4 mm. Adds approximately .5 cc of deadspace.

Setting Adapter Type

The *TidalGuard™ Sp* uses two types of adapters: Regular (Adult) and Exotic (Neonatal). Press the Adapter key to access the adapter menu, then the SELECT key to move the arrow pointer to the correct type. The selected adapter type is displayed in the message area in the center of the display screen.



If the adapter type placed on the CAPNOSTAT® CO_2 sensor does not match the currently selected adapter type, a "CHECK ADAPTER" message will appear. If the adapter type is correct, see the "Adapter Zero Procedure" on page 22.

Adapter Zero Procedure

An adapter zero allows the monitor to accommodate the optical characteristics of each different type of adapter. Before zeroing, verify the selected adapter type is correct, and the adapter setting is correct.

NOTE

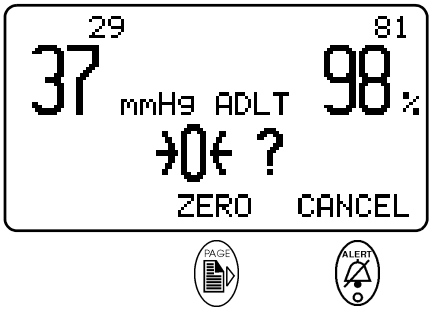
- This procedure is to be performed with a new unused adapter only! Perform this procedure only if the CHECK ADAPTER message persists, or if deemed necessary by qualified personnel.
- Do not perform this procedure while the CAPNO WARMING message is displayed.
- Do not perform this procedure while the adapter is connected to a breathing circuit or mouthpiece.
- The Regular (adult) and Exotic (neonatal) adapters must be zeroed independently (ensure that the proper adapter type is selected).
- If an adapter leaks or becomes occluded, replace and discard the occluded adapter.

1. Attach the selected adapter type to the CAPNOSTAT® CO_2 sensor. Select the adapter type (Regular, [adult] or Exotic [neonatal]) to be zeroed by pressing the Adapter key to access the adapter menu. Press the SELECT key to move the arrow pointer to the correct type of adapter and confirm the selection with the EXIT key.
2. Press and hold the Adapter key for five seconds to enter the zero menu.

WARNING

- Zeroing with the incorrect adapter type will cause incorrect readings.
- Zeroing the wrong adapter type on the wrong adapter setting will cause incorrect readings.
- Do not zero the CAPNOSTAT® CO_2 sensor without an adapter attached. Incorrect readings or no readings will result.

3. With all sources of CO_2 away from the adapter (including the patient's - and your own - exhaled breath), press the PAGE ZERO key to begin the procedure or ALERT CANCEL to exit.



NOTE

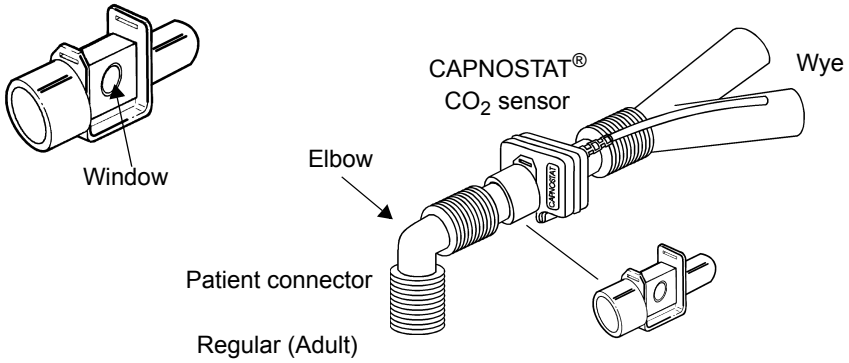
- If breaths are detected while attempting to zero the adapter, the icon will display and the zero menu will be exited automatically (remove the CO_2 source, wait 15 seconds and repeat the procedure from step 1).
- If the sensor is not at the proper temperature, the icon will display and the zero menu will be exited automatically (wait 15 seconds and repeat the procedure from step 1).
- The *TidalGuard*™ *Sp* will return to monitor mode automatically when the procedure is complete.

CAPNOSTAT® CO_2 Sensor and Airway Adapter Setup

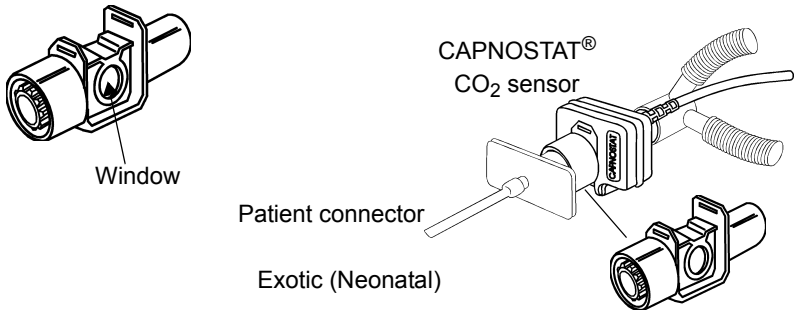
Patients requiring mechanical ventilation:

1. Select a new airway adapter.
   (Regular (Adult) - Cat. No. 6063 for ET tube size greater than 4.0 mm - see **Fig. 1**)
   (Exotic (Neonatal) Cat. No. 6312 for ET tube size 4.0 mm or less, see **Fig. 2**)
   Verify that the windows are clean and dry. Place the airway adapter in the patient's ventilator circuit. It should be positioned between the ET tube elbow and the circuit "wye" with its window in a vertical position.
   NOTE: In a regular (adult) or exotic (neonatal) ventilator's circuit, the elbow may not be present (**Fig. 2**).
2. Be sure the airway adapter is positioned vertically and located so that patient secretions and condensated water will flow **AWAY** from the adapter's windows, not through or into it.
3. Snap the CAPNOSTAT® CO_2 sensor onto the airway adapter.
4. Capnogram (CO_2 waveform) or $EtCO_2$ trend, $EtCO_2$ values, and respiratory rate should be displayed on the monitor.

(Fig. 1) Regular (adult) airway adapter Cat. No. 6063



(Fig. 2) Exotic (neonatal) airway adapter Cat. No. 6312

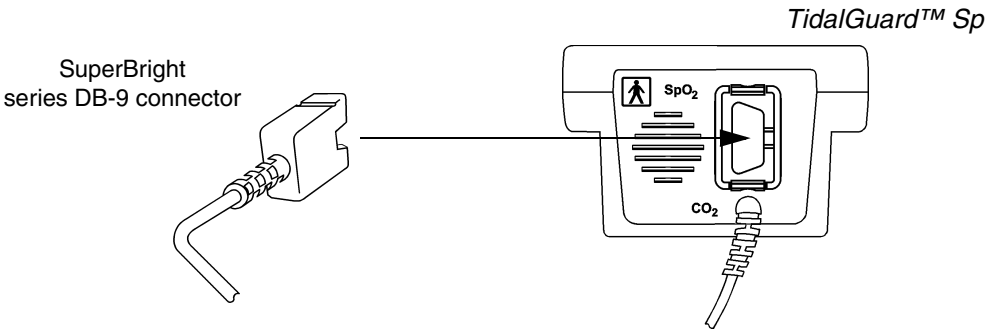


SpO_2 Sensors

CAUTION

Connect only approved SpO_2 sensor extension cables and/or SuperBright™ SpO_2 sensors to the *TidalGuard™ Sp.* Do not use other SpO_2 sensors or accessories with *TidalGuard™ Sp*. Before connecting to the patient or to the monitor, ensure that sensor extension cables and/or sensors are physically intact, with no broken, frayed or damaged components.

Plug the connector into the end panel SpO_2 sensor input. The sensor connector is keyed to fit into the input in only one direction.

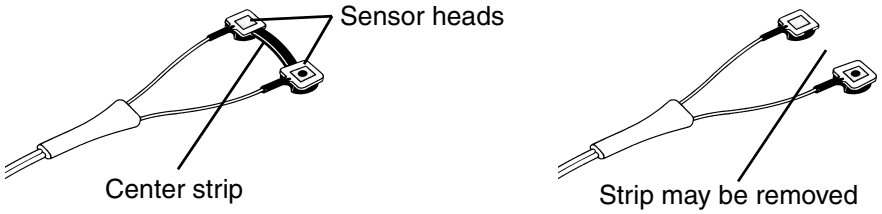


The connector clicks into place when properly seated. Sensors may be connected or removed whether or not the monitor is turned on.

Y-Sensor™

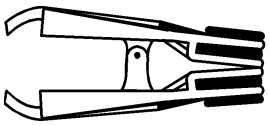
The reusable Y-Sensor is a flexible sensor designed for use on any patient. It is secured to the patient using a lingual clip (see below).

The Y-Sensor center strip is not a functional part of the sensor. Its twofold purpose is to aid in the placement of the sensor into the Y-Strip or other securing system and to keep the distance between the sensor heads to no more than 25mm. The center strip may be removed (carefully cut away) if the distance between the sensor heads needs to be reduced to less than 25mm.



Y-Sensor™ Applicators

The flexible and versatile Y-Sensor™ is applied to the patient using the Lingual Clip applicator.

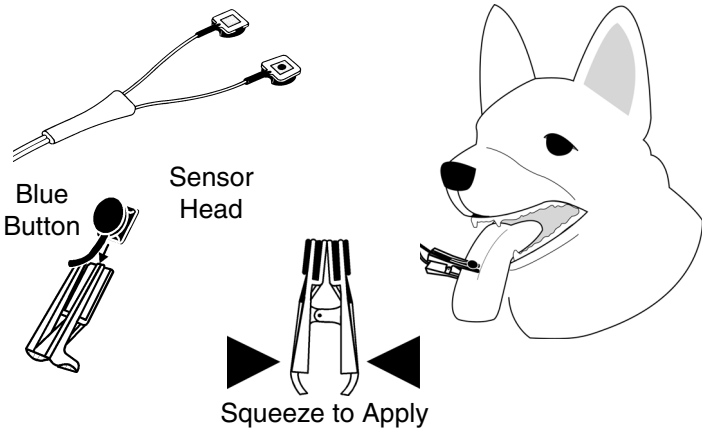


6131-00: Lingual Clip

Using the Lingual Clip:

1. Slide each Y-Sensor™ head into a Lingual Clip receptacle with the blue button facing outward.
2. Open the clip by squeezing its ends and applying it to the tongue.

   It may be necessary to rub the tongue with your fingers in order to increase circulation prior to applying the sensor.



Y-Sensor™ Quick Check

1. With the Y-Sensor™ connected to the monitor, but not applied to the patient, position the sensor heads so that they face each other (the red light shines at the detector). Is “SPO2 PRB OFF PAT” displayed?
2. Tape the Y-Sensor™ to your index finger. Does the monitor show reasonable SpO_2 and pulse rate values?
3. A YES to BOTH #1 and #2 indicates that the sensor is working properly. Apply the sensor to the patient as instructed above. The quick check is also a functional test of the extension cable.

Section 5 Monitoring

Display of Data

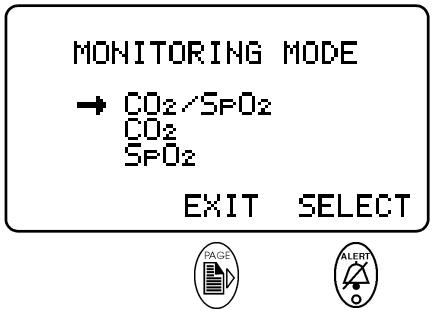
The *TidalGuard™ Sp* measures and displays $EtCO_2$, respiration rate, saturation and pulse rate. Until valid data is received for any parameter, that parameter will show a dash "--". When valid data is received, the value will display. If the parameter is lost, the value will return to dashes "--".

This will also occur when the monitor is first turned on and before any valid patient data is obtained. When monitoring, if valid data is received then lost for $ETCO_2$, respiratory rate, SpO_2, or pulse rate, an alert condition will occur. If the Alert key is pressed, and valid data is still not available, the numeric value of the parameter in question will display "--". If the key is not pressed within 30 seconds after the loss of data, the display will automatically turn to dashes "--".

Monitoring Mode

Three monitoring modes are available for the *TidalGuard™ Sp:* CO_2/SpO_2, CO_2 and SpO_2. The factory default is CO_2/SpO_2. To choose a different mode, press and hold the Power key to access the menu. The currently selected mode will flash. Press the SELECT key to move the arrow pointer to the correct mode and the EXIT key to exit the menu.

When the monitor is in CO_2 mode, SpO_2 screens are not be available; in SpO_2 mode, CO_2 screens are not available. All screens are available in CO_2/SpO_2 mode.



NOTE

Significant power savings can be realized by shutting down monitor functions that are not currently being used. Refer to "Battery Life and Recharge Times" on page 14.

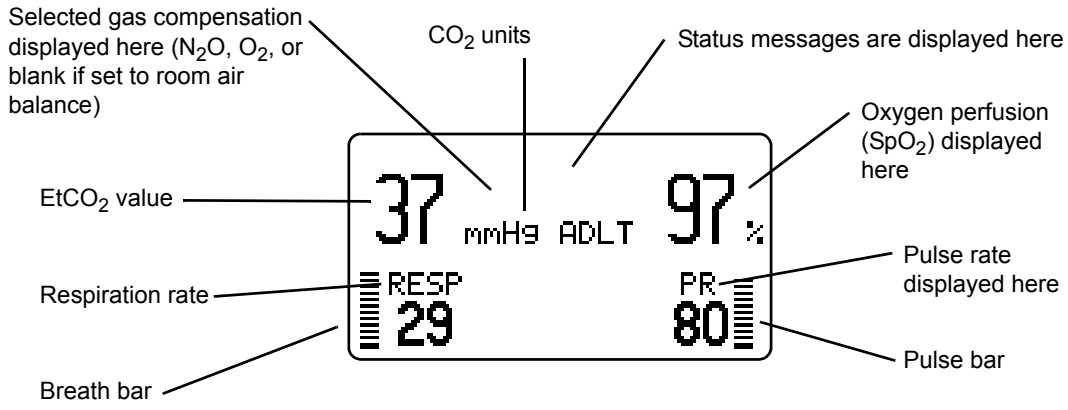
Parameters are measured and displayed on the various screens in the following sections.

Screen Displays

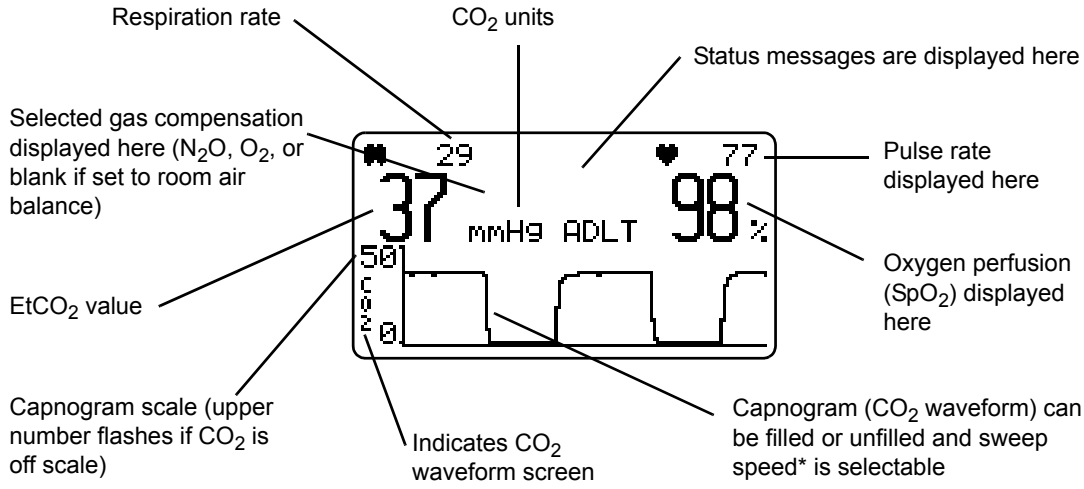
The last screen used will automatically appear on power-up, with the exception of the Trend screens.

Data Screen

The Data screen displays End Tidal CO_2, respiration rate, oxygen saturation, and pulse rate in larger, easy-to-read text, without waveforms. A pulse bar that is proportional to the signal strength, appears in the lower right corner, indicating the patient's pulse; a breath bar in the lower left corner indicates the patient's inhaled and exhaled breaths.



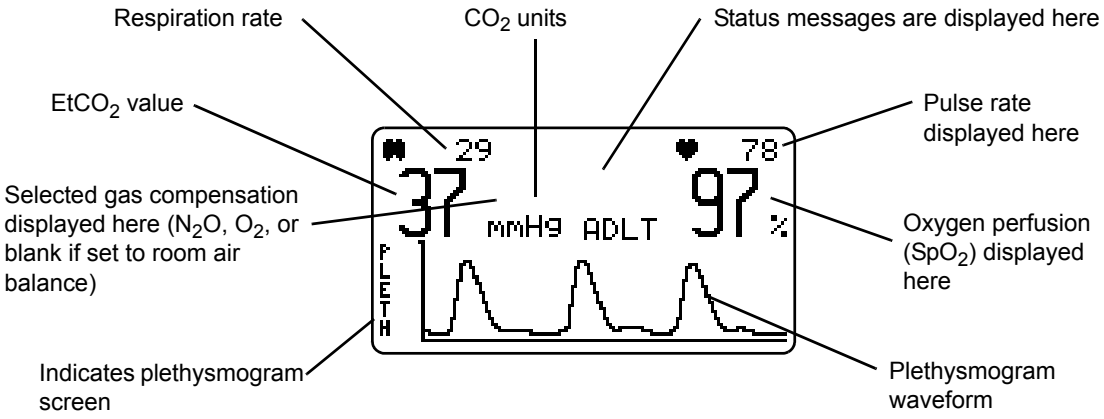
CO_2 Waveform Screen (Capnogram)



*NOTE: The capnogram sweep speed is automatically adjusted when switching modes. It will increase one step when switched from regular (adult) to exotic (neonatal), and decrease one step when switched from exotic (neonatal) to regular (adult).

SpO_2 Waveform Screen (Plethysmogram)

The pitch of the (user selectable) Pulse Rate "beep" tracks the SpO_2 value. Decreasing SpO_2 values are signaled by lower-pitched beeps; increasing values are signaled by higher-pitched beeps. The plethysmogram waveform is proportional to the signal strength.



Trend Screens

On-screen trends are displayed as a graph. Use the key to advance to the $EtCO_2$, Respiration Rate or SpO_2 trend screen. Thirty (30) minutes of data are displayed, moving from right to left on the screen.

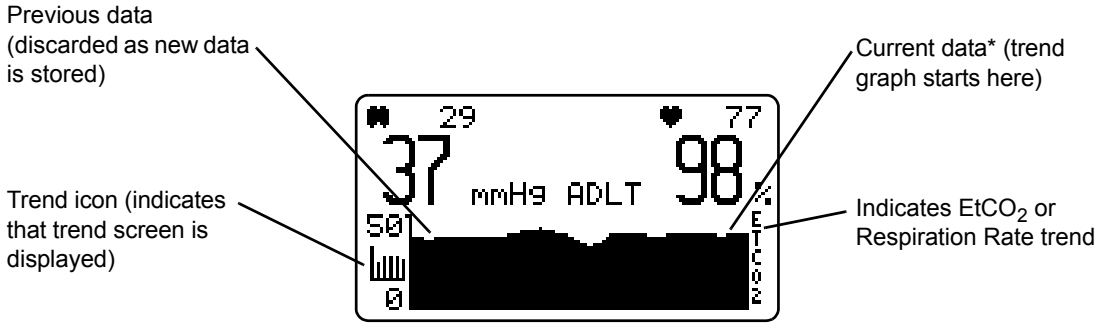
Each data point represents 16.8 seconds. New data is added on the right side of the screen. Refer to the CONFIGURATION menus for scale adjustment.

NOTE

Changing the CO_2 UNITS in the Configuration menu will result in a loss of all stored data.

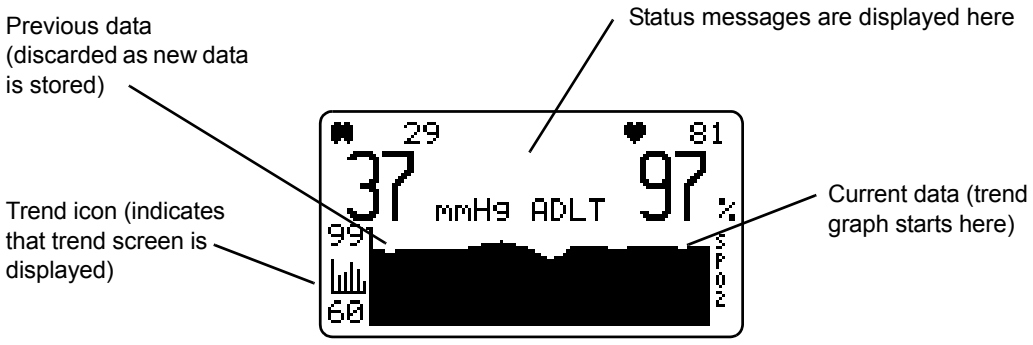
When changing CO_2 UNITS in the Configuration menu, the message "WARNING: CHANGING CO2 UNITS ERASES STORED TRENDS" will display. Press the OK key to acknowledge the warning (this does not erase the data), and return to the CO2 UNITS menu. Select the correct unit or press to EXIT.

$EtCO_2$ and Respiration Rate Trend Screen



* Thirty (30) minutes of data are displayed moving from right to left on the screen. Each data point represents 16.8 seconds.

SpO_2 Trend Screen



Trend Memory

In addition to on-screen trends, the *TidalGuard™ Sp* has internal, battery-backed, trend memory that stores $EtCO_2$, respiration rate, SpO_2 and pulse rate calculated parameters for 24 hours at an eight second resolution. The chart below describes the storage interval for each parameter. Stored parameter values can be downloaded (transferred) to a PC and viewed using the optional NovaCARD software. See "RS232 Options" on page 39 for more information.

To erase stored trends; hold both and keys during the power up cycle until "ERASING STORED TRENDS" appears on the display.

Trending Storage Interval	
$ETCO_2$	Maximum value
Resp. Rate	Average
Inspired CO_2	Maximum value
SpO_2	Average
Pulse Rate	Average

Messages

Status Messages

Status messages indicate conditions that should be corrected or monitored; they may or may not be tied to an alert condition. These conditions can be a result of a hardware or sensor fault condition. Status messages are displayed on the screen in the same manner as alert messages. Following is a list of status and alert messages that may appear on the monitor.

System Messages

Message	Description
PRESSURE FAULTY	The barometric pressure sensor is returning a value which is out of range (<400 mmHg or > 800 mmHg). The monitor will default to 760 mmHg for calculation purposes. Refer servicing to qualified personnel.
EtCO2 AUTO LIMITS SET SpO2 AUTO LIMITS SET	This message is displayed when the monitor has successfully determined and set the auto alert limits for SpO_2 and $ETCO_2$.
RESETTING TO FACTORY DEFAULTS	All setup and alert settings have just been reset to factory default values.
ERASING STORED TRENDS	The trends stored in the monitor's memory have been erased.
CHECK CLOCK TIME AND DATE	Time and date may not be properly set. The time and date can be adjusted in the CONFIGURATION menu by pressing the Backlight key. See "Configuration Settings" on page 17.
AUTO POWER OFF IN X:XX	The monitor will shut off if there is no CO_2 breath detection or key depressions for ten minutes from when the unit powers on. The timer (X:XX) will then count down from two minutes to zero. Pressing the adapter key, or detection of a CO_2 breath will cancel the shutdown.
UNKNOWN ERROR	Remove the monitor from use and contact service personnel.

Capnography Messages

Message	Description
CAPNO WARMING	Sensor is under temperature. Wait for the CAPNOSTAT® CO_2 sensor to reach operating temperature.
CHECK ADAPTER	Excessive moisture or secretions detected in the adapter: Change adapter. Adapter type has been changed (e.g. regular [adult] to exotic [neonatal]): Zero the adapter. No adapter detected: Place an adapter on the CAPNOSTAT® CO_2 sensor.
RESP=0 m: ss	A breath has not been detected for the indicated time (XX seconds). This message appears when the time since the end of expiration of the last detected breath exceeds the NO RESP TIMER setting in the configuration menu. See "Configuration Settings" on page 17.
INSP XX	An inspired CO_2 level of 3 mmHg (or 0.4% or kPa) was detected for 20 consecutive seconds.
ZRO: HOLD ADPT KEY	The current through the CAPNOSTAT ®CO_2 sensor source emitter has changed or the system is detecting $EtCO_2$ values less than -3.0 mmHg.

Message	Description
CAPNO FAULTY	The following errors may be present: 1. The current through the source is too high or low. 2. The checksum for the CAPNOSTAT® calibration data is wrong. 3. The revision of the calibration data in the CAPNOSTAT® is not compatible with the software in the *TidalGuard™ Sp* Monitor. Refer servicing to qualified personnel.
CAPNO HI TEMP	The temperature of the case or detector heater is over 50°C. Refer servicing to qualified personnel.
CAN NOT ZERO CO2	An error was detected which did not allow the system to zero the current adapter being used. Refer servicing to qualified personnel.
CO_2 OUT OF RANGE	The detected waveform value is beyond the measurement range of the monitor (0-100 mmHg, 0-13.2% or kPa).
	A changing level of CO_2 was detected during an adapter zero procedure. Wait 30 seconds and retry.
	The CAPNOSTAT® CO_2 sensor has not reached operating temperature while attempting to zero. Wait for the sensor to reach operating temperature.
ADAPTER ZERO IN PROGRESS, TIME REMAINING 0 : XX	An airway adapter zero is in progress. XX indicates the number of seconds remaining.
WARNING: CHANGING CO2 UNITS ERASES STORED TRENDS	Changing CO_2 units (mmHg, %, kPa) in the Configuration menu will cause this message to appear.

Oxygen Saturation Messages

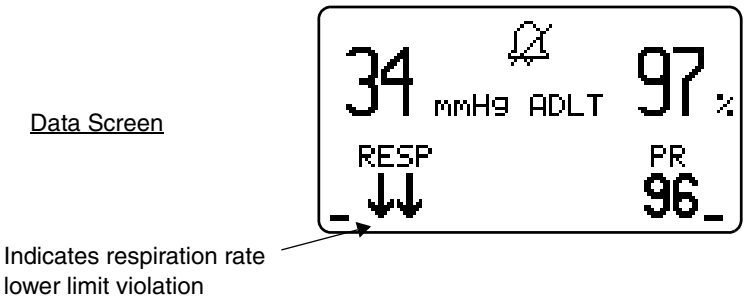
Message	Description
SPO2 LOW STRENGTH	The pulse strength as detected by the sensor is too small for proper monitor operation. This message will disappear when the problem is corrected.
INSUFF LIGHT	Sensor is placed on a site too thick (opaque) for adequate light transmission. Move sensor to a different site.
PULSE RANG ERR	Pulse must be within 30-250 beats per minute, inclusive.
SHIELD SPO2 PRB	Ambient light source (sunlight, warming lights, etc.) are interfering with sensor operation. Shield sensor from these light sources.
SPO2 PRB FAULTY	Remove sensor from use and contact qualified service personnel.
SPO2 BAD SIGNAL	Monitor not receiving valid signals from the sensor. May be caused by excessive motion, cardiac arrhythmia or other situations leading to poor signal.
CONNECT SPO2 PRB	Sensor not connected to unit.

Message	Description
SPO2 PRB OFF PAT	Sensor not on patient.
MONITOR FAULTY	Remove the monitor from use and contact qualified service personnel.

Alerts

Alerts are generated for $ETCO_2$, respiration rate, SpO_2, and pulse rate. These alerts occur when the high or low limits for a particular parameter are exceeded. There is also an alert when there is a loss of pulse rate, or when there is a loss of respiration for a consecutive twenty seconds (other limit times may be selected for the NO RESP TIMER, see "Configuration Menus" on page 16). Alert messages are displayed in the message center or in the particular area of the display when they occur. For example, a RESP=0 message will be displayed in the respiration section of the screen.

When any of the parameters are violated with alert limits ENABLED, two up ↑↑ or two down ↓↓ arrows will replace the parameter, indicating whether the violation was above or below the alert limit.



Setting Alert Limits

The alert limits for the monitor can be manually or automatically adjusted. To access AUTO ALERTS or SET ALERTS, the alert limits must be ENABLED from the Configuration menu. See "Configuration Menus" on page 16.

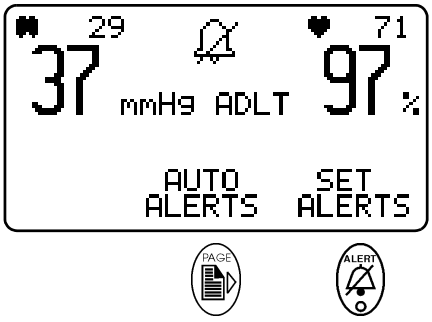
NOTE

To configure the monitor with the default limit values, power up while pressing and holding the Backlight and Alert keys. This will cause all parameters to return to their default values.

Manually Setting Alert Limits

Press the Alert key to access the ALERT menu. Press the SET ALERTS softkey to display the SET ALERT LIMITS menu. When selected, this screen will appear for 3 seconds, then automatically return to the previous display.

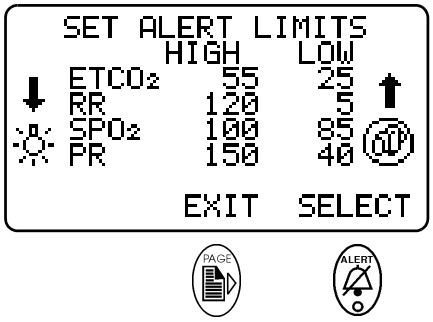
Alert Screen



Using the menu control keys, adjust the settings as desired: press the SELECT key to move to the desired parameter for adjusting; the selected parameter will flash. Use the Backlight key to decrease ↓ a parameter value and the Adapter key to increase ↑ the selected value.

Maximum and minimum high and low limits are preset for each parameter and cannot be exceeded. Also, the range between high and low alert limits is restricted to a minimum of five units. For example, default $ETCO_2$ settings are, high: 55 mmHg, low: 25 mmHg. If the user decreases the high setting to 30 mmHg (within 5 units of the low setting), and continues to lower the setting, *both* high and low $ETCO_2$ settings will decrease, maintaining the five unit range.

Selected parameter will flash



Default values are shown

NOTE

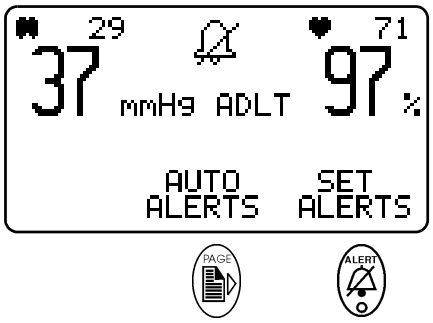
When the monitor is turned off, manual alert limit settings will be retained, even if AC power and the battery are disconnected.

Alert Limits Ranges	
$ETCO_2$	150 max 10 min
Resp. Rate	150 max 5 min
SpO_2	100 max 50 min
Pulse Rate	249 max 30 min

Auto Alert Limits

To set alert limits automatically, press the Alert key, and "AUTO ALERTS" will appear over the Page key. Press the Page key, and "ENABLE AUTO ALERTS?" will appear. Press "YES." The monitor will automatically set alert limits based on recent patient data.

Alert Screen



The screen will display "ETCO2 AUTO LIMITS SET" and "SPO2 AUTO LIMITS SET" messages. Press CONTINUE to return to the previous screen. If auto alert limits cannot be determined for one or both limits, the message "ETCO2 AUTO LIMITS NOT SET" and/or "SPO2 AUTO LIMITS NOT SET" will appear.

If one or both of the screen messages say "LIMITS **NOT** SET," exit this screen, resume monitoring and retry in 30 seconds when the monitor has collected sufficient data.

NOTE

Auto Alert Limits are not stored by the monitor. If Auto Alert Limits are selected and the unit is powered down, default limits will appear on power up, regardless of stored values.

Alert Audio

A NO RESPIRATION alert will sound after 20, 40 or 60 seconds (depending upon the configuration setting) if no breaths are detected. When this occurs a RESP=0 timer appears, indicating the number of seconds since the last detected breath. Three breaths must first be detected to initialize this alarm.

An audible alert is generated any time an alert condition is detected, provided that neither the 2 minute suspend, nor the audible alert muting are enabled. If the ALERT VOLUME is set to DISABLED, an audible alert is not generated, and the alert silence LED will flash red.

Press the Alert key to suspend an audible alert for 2 minutes. Press again to cancel.

Press and hold the Alert key to disable audible alerts. Press and hold again to cancel. The monitor will always power up with the audible alerts settings retained in memory.

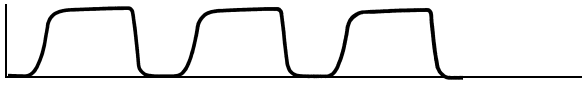
The audible alert volume can be adjusted or disabled from the CONFIGURATION menu. Press the Backlight and Adapter keys simultaneously, then the Page key until the ALERT VOLUME menu appears.

NOTE

Make sure that the audible alert volume is not set too low to be heard over ambient noise levels.

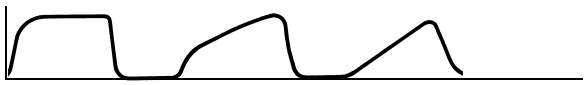
Capnogram Sample Waveforms and Interpretations

Normal: The "normal" capnogram is a waveform that represents the varying CO_2 level throughout the breath cycle.



Rebreathing: Elevation of the baseline indicates rebreathing (may also show a corresponding increase in $EtCO_2$).

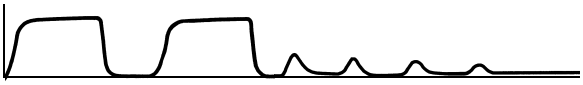
Obstruction: Obstructed expiratory gas flow is noted as a change in the slope of the ascending limb of the capnogram (the expiratory plateau may be absent).



Endotracheal tube in the esophagus.

Inadequate seal around endotracheal tube: The downward slope of the plateau blends in with the descending limb.

Accidental extubation:



Reference Handbooks

For a discussion on waveform interpretations, refer to the Reference Handbooks on capnography, respiratory mechanics, and pulse oximetry. Contact Customer Service or your local sales representative for more information.

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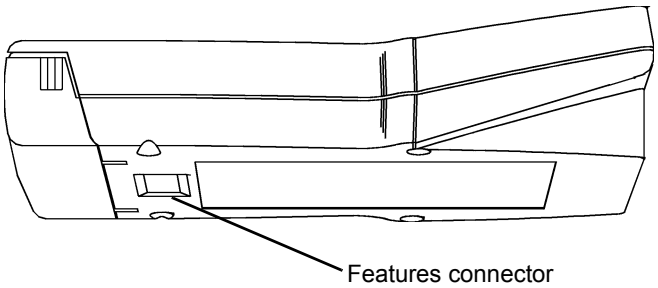
Section 6 *RS232 Options*

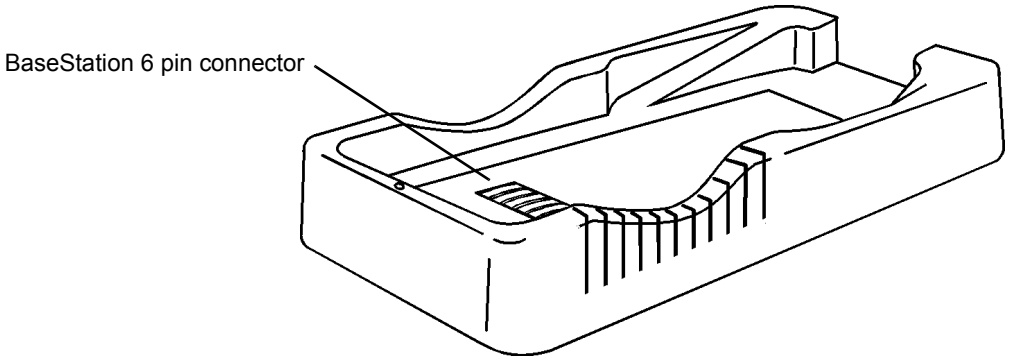
Power and RS232 Serial Port Communications

A serial communications mode is available for the *TidalGuard™ Sp*. The NovaCOMM Interface is designed to output data in formats easily read by a computer. The monitor must be placed in the BaseStation (PN: 6998-00) to use the serial communication mode.

Located on the BaseStation is a six pin modular contact which provides an RS232 interface as well as a power output for unit operation and battery charging when connected to hand-held monitors. This connector meets the patient safety requirements of IEC 60601-1.

When the monitor is placed within the BaseStation, contact is made between the 6-pin connector in the BaseStation and the Features connector on the bottom of the monitor. This connection is transferred to the "RS232 Serial Port" connector on the BaseStation.

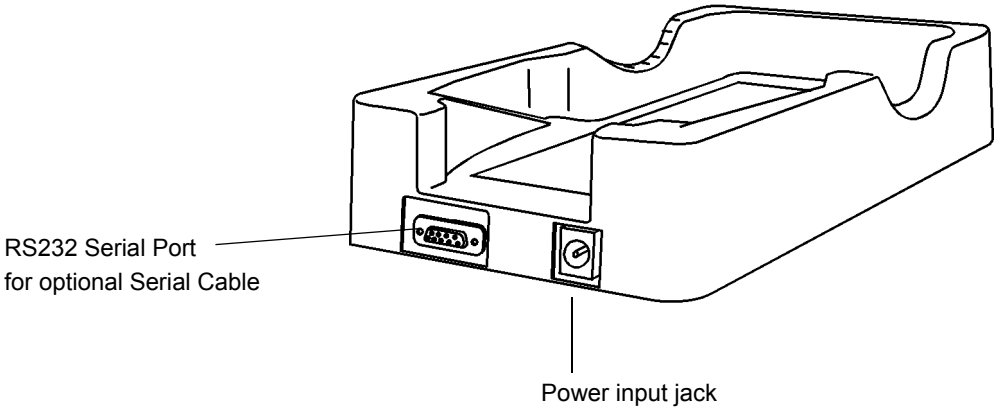




WARNING

Patient safety may be compromised if an external device (e.g. printer or computer) is connected to the RS232 serial port on the BaseStation.

The “RS232 Serial Port” 9 pin D connector allows connection to a host computer.



Downloading Data to a PC

1. Connect the Serial Cable (PN: 600075, sold separately) to the RS232 Serial Port connector on the BaseStation.
2. Connect the external power supply to the power input jack on the BaseStation, then connect a line cord from the power supply to an AC source. It is recommended that the monitor be powered by the BaseStation using the external power supply when downloading data from the monitor or updating software. This will prevent power loss from a depleted battery.
3. Plug the other end of the serial cable into the host computer.
   NOTE: The COM port on the computer will be either a 9 pin or a 25 pin D connector. Use an adapter if the COM port on the host computer does not match the connector on the end of the Serial Cable.
4. Set the monitor inside the BaseStation, verify the “In Use” ∿ LED illuminates. Refer to the 6993-23 BaseStation User’s Manual for more information.

Section 7 Maintenance

Cleaning and Sterilization

Follow the cleaning and sterilization instructions listed below to clean and/or sterilize the monitor and its accessories.

Monitor, BaseStation and External Power Supply

- Turn the monitor off, and unplug the BaseStation and the external power supply from the AC power source before cleaning.
- The monitor, BaseStation and external power supply can be cleaned and disinfected by wiping with solutions such as a 70% isopropyl alcohol, 2% gluteraldehyde, or 10% bleach solution. Wipe down with a water-dampened clean cloth to rinse. Dry before use.
- Do not immerse the monitor, BaseStation or external power supply.
- Do not attempt to sterilize the monitor, BaseStation or external power supply.

SpO_2 Y-Sensor

- Do not immerse connector on the Y-Sensor.
- The Y-Sensor may be immersed—up to, but not including, the connector, in a 2% gluteraldehyde solution, or 10% bleach solution. Refer to manufacturer's instructions and standard hospital protocols to determine recommended times for disinfection and sterilization.
- Rinse thoroughly with water and dry before use (do not rinse the connector).
- Do not attempt to sterilize Y-Sensor except as stated above.
- After cleaning or sterilizing the Y-Sensor, verify that the sensor is physically intact, with no broken or frayed wires or damaged parts. Make certain that the connectors are clean and dry, with no signs of contamination or corrosion. Do not use a broken or damaged sensor or one with wet, contaminated, or corroded connectors.
- Perform a "Quick Check" to verify the integrity of the sensor (see "Y-Sensor™ Quick Check" on page 26).

Lingual Clip

- Do not immerse the lingual clip
- Clean the lingual clip with a cloth dampened with 70% isopropyl alcohol. After cleaning wipe the lingual clip down thoroughly with a clean water dampened cloth to rinse.

CAPNOSTAT® CO_2 Sensor

- Clean the sensor surface with a damp cloth.
- Make certain that the sensor windows are clean and dry.
- Do not immerse the CAPNOSTAT® CO_2 sensor.
- Do not attempt to sterilize the CAPNOSTAT® CO_2 sensor.

Battery Maintenance

If the monitor has not been used or powered by the external power supply for an extended time* (3 months or more) allow the battery to charge before use or replace the battery with a fully charged battery and continue monitoring. The monitor may not power up on battery power if the battery is not sufficiently charged. Refer to "Battery Life and Recharge Times" on page 14 for charging times and instructions.

Maintenance Schedules

When the monitor powers up, a self-test is performed which checks the internal electronics of the monitor. If this self-test fails, remove the monitor from use and contact qualified service personnel.

The monitor should undergo routine inspection and safety checks on a quarterly basis or according to hospital protocol. The *TidalGuard™ Sp* Service Manual (Catalog No. 9110-90/9146-90) contains procedures and safety test instructions, component parts lists, circuit diagrams, theory of operation and other information to assist qualified service personnel in servicing the monitor.

WEEE/RoHS Recycling Directives

Waste electrical and electronic equipment and restriction of the use of certain hazardous substances in electrical and electronic equipment (WEEE/RoHS) recycling directives.

Compliant with the WEEE/RoHS recycling directives.

If you are subject to the WEEE/RoHS directives, refer to www.respironics.com for the passport for recycling this product.

*The internal battery will slowly discharge over long periods of non-use.

Section 8 *Specifications*

General

Specifications for the *TidalGuard™ Sp* Monitor, are listed for informational purposes only, and are subject to change without notice.

Capnograph

- Principle of Operation: Non-Dispersive Infrared (NDIR) absorption, dual wavelength ratiometric-single beam optics
- Sensor Type: "Mainstream" (no gas sample drawn from breathing circuit)
- Initialization Time: Capnogram in 15 seconds, full specifications in 60 seconds.
- Response Time: 60 ms
- Gas Compensation - Room Air, O_2 > 60%, N_20 > 60%: Operator selectable in configuration screen.
- Barometric Pressure Compensation: Automatic (range 400-800 mmHg)
- CAPNOSTAT® CO_2 Sensor and Airway Adapter:
  Weight: Less than 18 g without cable
  Sensor Size: 1.3 x 1.67 x .85 inches (3.30 x 4.24 x 2.16 cm), 6 foot cable (1.83 m)
  Construction: Durable high performance plastic, ultra-flexible cable
  Shock Resistant: CAPNOSTAT® CO_2 sensor withstands a 6 foot drop to a tile floor
- Regular (Adult) Airway Adapter: Less than 5 cc deadspace, meets ANSI Z-79
- Exotic (Neonatal) Airway Adapter: Less than ½ cc deadspace, meets ANSI Z-79

$EtCO_2$ Section (Mainstream)

- Range 0-150 mmHg, CO_2 partial pressure
- Accuracy*: 0-40 mmHg ±2 mmHg, 41-70 mmHg 5% of reading, 70-150 mmHg ±8% of reading.
- Warm-up Time: Operational in 15 seconds, 1 minute to full specifications
- Step Response Time: 60 ms, regular (adult); less than 50 ms, exotic (neonatal)
- Averaging Time: 1 breath, 10 seconds (default), 20 seconds, instantaneous
- Display Resolution: 0-25, 0-50, and 0-150 mmHg in 31 pixels
- Alerts: User selectable alert limits for $EtCO_2$.

*Allows for halogenated anesthetic agents which may be present at normal clinical levels. The presence of desfluane in the exhaled breath beyond normal levels (5-6%) may positively bias carbon dioxide values by up to an additional 2-3 mmHg. Maintained up to 70 breaths per minute.

Respiratory Rate (Mainstream)

- Range 0-150 breaths/min.
- Accuracy: ±1 breaths/min.
- Alerts: The *TidalGuard™ Sp* has user selectable alert limits for Respiratory Rate.
- Averaging Time: 8 seconds

SpO_2 Section

- Range 0-100%
- Accuracy: 70-100% ±2% SpO_2; ±1 standard deviation; 0-69% unspecified
- Display Resolution: 1%
- Averaging Time: menu-selectable times of 2 and 8 seconds (default is 8 seconds)
- Audible SpO_2 Trend Feature: Pitch of (user selectable) pulse rate "beep" tracks the SpO_2 values (i.e. decreasing SpO_2 values are signaled by lower pitched "beeps").
- Settling Time: Display settles to within 1% of final reading less than 15 seconds after the sensor is properly applied.
- Alerts: The *TidalGuard™ Sp* will have user selectable alert limits for SpO_2.

Pulse Rate Section

- Range: 30-250 beats per minute (bpm)
- Accuracy: (1 standard deviation), 1% of full scale
- Display Resolution: 1 bpm
- Averaging Time: menu-selectable times of 2 and 8 seconds (default is 8 seconds)
- Settling Time: Display settles to within 1% of final reading less than 15 seconds after the sensor is properly applied.
- Alerts: The *TidalGuard™ Sp* will have user selectable alert limits for Pulse Rate.

Monitor Specifications

- Classification (IEC60601-1): Class I, internally powered, type BF, enclosure protection rating of IPX1**. Operating Environment: 50 to 104° F (10 to 40° C), 0-90% relative humidity (non-condensing)
- Transport/Storage:
  short term: 14° to 122° F (-10 to 50° C) with NiMH battery
  long term: 14° to 95° F (-10 to 35° C) with NiMH battery
  storage: 14° to 131° F (-10° to 55° C) without NiMH battery
- Size: 7.9" x 3.25" x 1.5"
- Weight: 24 ounces
- Power: 100-250 VAC, .38A, 50-60 Hz
- Battery: Rechargeable DR30 NiMH battery pack (Cat. No. 400043) or equivalent; AA lithium batteries - Energizer L91 or equivalent.

**External power supply excluded.

- Battery Life: Approximately 4.5 hours of continuous use with fully charged DR30 NiMH rechargeable battery pack.
- Display: LED backlit 2.5" x 1.25" LCD, adjustable contrast
- LED indicators for: Low battery, adapter type, audio/alert status (indicates audio off, 2 minute suspend, active alert), and external power.
- Electromagnetic Emissions: Conforms to Medical Device Directive 93/42/EEC, IEC60601-1-2 (2001), CISPR11 (1991), IEC61000-3-2 (2001), IEC61000-3-3 (2003)
- Electromagnetic Immunity: Conforms to Medical Device Directive 93/42/EEC, IEC60601-1-2 (2001), IEC61000-4-2 (1995), IEC61000-4-3 (2002), IEC61000-4-4 (2004), IEC61000-4-5 (1995), IEC61000-4-6 (2003), IEC61000-4-8 (1994), IEC61000-4-11 (2004)

Additional Features

- Audible SpO_2 Trend Feature: Pitch of Pulse Rate "beep" tracks the SpO_2 value, user selectable volume.
- Alert Limits: Automatic or menu selected high and low limits for $ETCO_2$, Respiratory Rate, SpO_2 and Pulse Rate. NO RESPIRATION alert selectable between 20, 40 and 60 seconds. Visible and audible alerts are immediate.
- 2-Minute Suspend: When  key is pressed, audible alerts are suspended for two minutes. Indicated by yellow 2 minute LED and flashing  bell icon
- Audio Off: Press and hold  key for 3 seconds to deactivate audible alerts. Indicated by flashing yellow Audio Off LED and flashing  bell icon.
- Trend Memory: 24 hour trend memory capacity, battery backed. On-screen 30 minute trends for $ETCO_2$, Respiration Rate and SpO_2. Other parameters are stored internally and can be downloaded to a PC.
- Digital Data Output: Serial (RS232), connect only to approved devices.
- Internal Battery-backed Real Time Clock

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Section 9 *Electromagnetic Compatibility*

Medical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this document.

The *TidalGuard™ Sp* monitor complies with IEC 60601-1-2:2001, providing reasonable protection against electromagnetic interference in a typical medical installation. The equipment generates, uses and can radiate electromagnetic interference (EMI), and if not installed and used in accordance with the instructions, may cause interference with other devices in the vicinity.

If interference does occur, correct it using one or more of the following measures:

- Move the receiving device or increase separation between the equipment.
- Consult Respironics or members of the hospital's engineering department for more information.

Warnings

- The use of portable and mobile radio frequency (RF) communications equipment can affect this and other pieces of medical equipment.
- The use of accessories, sensors and cables other than those specified by Respironics may increase emissions or decrease immunity of the equipment.
- The *TidalGuard™ Sp* should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.

Cautions

- Observe precautions for electrostatic discharge (ESD) and electromagnetic interference (EMI) to and from other equipment.
- Where electromagnetic devices (i.e., electrocautery) are used, patient monitoring may be interrupted due to electromagnetic interference. Electromagnetic fields up to 3 V/m will not adversely affect system performance.
- Sudden erratic changes in equipment performance that do not correlate to the physiological condition of the patient may be signs that the monitor is experiencing electromagnetic interference.

Electromagnetic Emissions

Guidance and manufacturer's declaration - Electromagnetic emissions		
The *TidalGuard™ Sp* is intended for use in the electromagnetic environment specified below. The customer or user of the *TidalGuard™ Sp* should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The *TidalGuard™ Sp* 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 equipment.
RF emissions CISPR 11	Class A	Class A: The *TidalGuard™ Sp* is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

Guidance and manufacturer's declaration - Electromagnetic immunity			
The *TidalGuard™ Sp* is intended for use in the electromagnetic environment specified below. The customer or user of the *TidalGuard™ Sp* should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the *TidalGuard™ Sp* requires continued operation during power interruptions, it is recommended that the *TidalGuard™ Sp* be powered from an uninterruptible power supply or a battery.

Guidance and manufacturer's declaration - Electromagnetic immunity (Continued)			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to the application of the test level			

Guidance and manufacturer's declaration - Electromagnetic immunity

The *TidalGuard™ Sp* is intended for use in the electromagnetic environment specified below. The customer or user of the *TidalGuard™ Sp* should assure that it is used in such an environment.

Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the *TidalGuard™ Sp*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strength 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 equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800MHz, 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 transmitters, such as base stations for radio (cellular, cordless) telephones and land mobile radios. amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the *TidalGuard™ Sp* is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal operation is observed, additional measures may be necessary, such as reorienting or relocating the *TidalGuard™ Sp*.

b. Over the frequency range of 150 kHz to 80MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the *TidalGuard™ Sp*

The *TidalGuard™ Sp* is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *TidalGuard™ Sp* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *TidalGuard™ Sp* as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (Watts)	**Separation distance according to the frequency of transmitter** (meters)		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated by using the equation applicable to the frequency of the transmitter, where *P* is the maximum power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800MHz, the separation distance for 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.