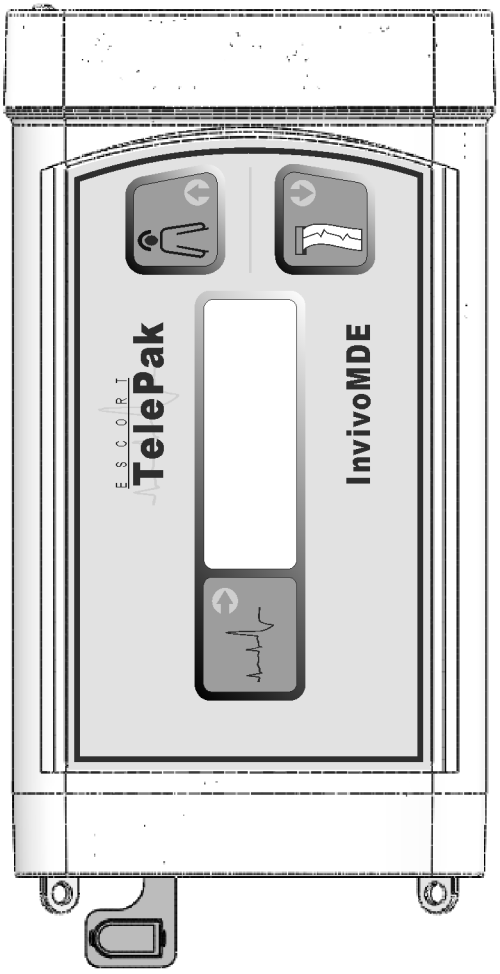
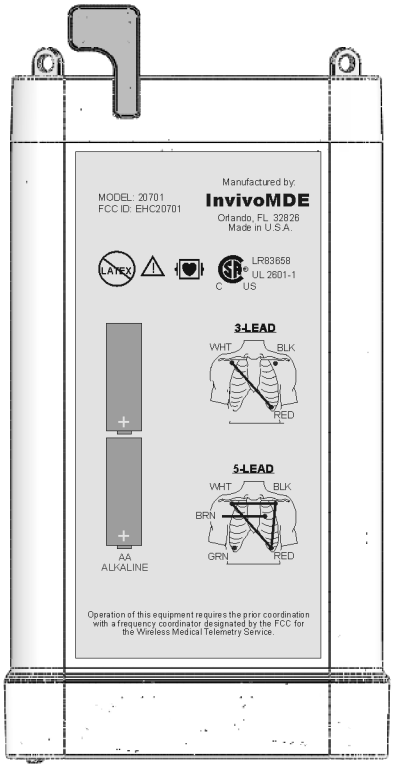
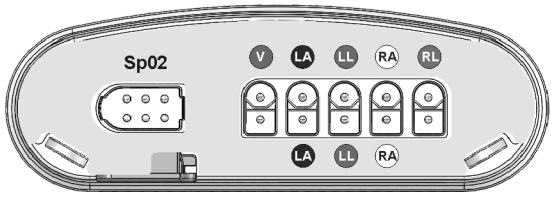
E9031-10

Vision TelePak™ Telemetry Transmitter







Operations Manual

Invivo™

Invivo Corporation

VISION TelePak TELEMETRY TRANSMITTER

OPERATIONS MANUAL

Model Number 20701

Invivo™

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Invivo PN# E9031-10
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EQUIPMENT CLASSIFICATION

Classification according to IEC-60601-1	
According to the type of protection against electrical shock:	Class I equipment.
According to the degree of protection against electrical shock:	Type CF (defibrillator-proof) equipment.
According to the degree of protection against harmful ingress of water:	Ordinary equipment (enclosed equipment without protection against ingress of water).
According to the methods of sterilization or disinfection:	Non-sterilizable. Use of Liquid surface disinfectants only.
According to the mode of operation:	Continuous operation.
Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.	

Precautions

General

Federal law in the USA or Canada restricts this device to sale by, or on, the order of a physician.

The Alkaline AA batteries powering the VISION TelePak are consumable components and must be replaced regularly to ensure proper operation. Dispose used batteries properly, according to local regulations.

Use only high-quality, 1.5V size AA Alkaline batteries in the VISION TelePak. Use of other batteries may shorten battery life.

Read and understand this manual before using the VISION TelePak device.

Explosion hazard. Do not use VISION TelePak in presence of flammable anesthetics.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Electromagnetic interference (EMI) may affect the performance of this device. Special care should be taken when electro surgical instruments or similar devices are used on a patient wearing any telemetry transmitter.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: 1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

ECG

Care should be taken to ensure that leadwires remain firmly attached to both transmitter and electrodes. Ensure that electrodes maintain good contact with the patient's skin, and that electrodes are properly placed and connected to unit. Failure to do so may prevent ECG signal from being received, or give incorrect results.

For pacemaker patients, HR may continue to count pacemaker artifact during cardiac arrest or other arrhythmia. Keep pacemaker patients under close surveillance.

Telemetry should not be used for primary monitoring in applications where the momentary loss of the ECG is unacceptable.

If the ECG lead is disconnected from the patient or VISION TelePak, no ECG signal will be available.

Poor placement of the ECG leads, or incorrect ECG sizing, could result in a poor or absent ECG signal.

Creased or stretched ECG leads, or excessive patient movement, could result in a noisy ECG signal.

Precautions

SpO2

Use only NONIN™ SpO2 sensors specified for VISION TelePak.

Incorrect sensor application or use may cause tissue damage or improper operation of the transmitter. Follow directions for use provided.

Incident light, poor perfusion, and other factors may affect SpO2 performance and accuracy.

Inaccurate measurements or loss of pulse signal may be caused by:

- Incorrect sensor application or use.
- Significant levels of dysfunctional hemoglobins (HbCO or MetHb).
- Intravascular dyes such as indocyanine green or methylene blue.
- Darkly pigmented skin or nail polish.
- 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 illumination can be corrected by covering 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.
- Hypotension, severe vasoconstriction, severe anemia, or hypothermia.
- Arterial occlusion proximal to sensor.
- Patient in shock.

For continuous SpO2 monitoring, high and low alarms must be set and monitored at the ESCORT Vision central station.

Use only NONIN manufactured PureLight® pulse oximeter sensors. These sensors are manufactured to meet the accuracy specifications for NONIN pulse oximeters. Using other manufacturers' sensors can result in improper pulse oximeter performance.

As with all medical equipment, carefully route cables and connections to reduce the possibility of entanglement or strangulation.

This device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed carefully to verify normal operation.

The Xpod has motion tolerant software that minimizes the likelihood of motion artifact being misinterpreted as good pulse quality. In some circumstances, however, the Xpod may still interpret motion as good pulse quality.

Inspect the sensor application site at least every six (6) to eight (8) hours to ensure correct sensor alignment and skin integrity. Patient sensitivity may vary due to medical status or skin condition. Discontinue use of adhesive tape strips if the patient exhibis an allergic reaction to the adhesive material.

This product will perform in conformity with the description thereof contained in this operating manual and accompanying labels and/or inserts, when assembled, operated, maintained, and repaired in accordance with the instructions provided.

USER RESPONSIBILITY

This product must be checked periodically for proper operation. A defective or questionable 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, Invivo recommends that a telephone call or written request for service be made to the factory or nearest service center. Invivo's toll free number is: (800) 331 - 3220 or (407) 275 - 3220, ask for Technical Assistance.

This product or any of its parts should not be repaired other than in accordance with written instructions provided by Invivo or altered without the prior written approval of Invivo.

The user of the 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 Invivo or Invivo authorized service personnel.

Indications for Use

The Vision TelePak Telemetry Transmitter is a portable monitor intended to be used for monitoring vital signs (ECG and SpO2) of critically ill adult and pediatric patients in the hospital environment.

Accessories

VISION TelePak Telemetry Transmitter

Item Description	Part Number
VISION TelePak Shielded 5-Leadwire Set	E2910-50
VISION TelePak XPod SpO2 Patient Cable	E2910-51
VISION TelePak 8000A Clip Finger Sensor (for use with E2910-51)	E2910-52
VISION TelePak IPod SpO2 Cable/Sensor (complete)	E2910-53

SECTION 1
VISION TelePak TELEMETRY TRANSMITTER

1.0 VISION TelePak™ TELEMETRY TRANSMITTER.

1.1 Introduction. The VISION TelePak™ telemetry transmitter is intended only as an adjunct to patient assessment. It cannot replace skilled nursing care and proper surveillance. Carefully read this operator's manual, all directions for use of the VISION TelePak, Invivo monitors and monitor accessories, and all precautionary information before attempting clinical use of the VISION TelePak. Always keep high-risk patients under close surveillance.

The VISION TelePak is capable of providing continuous measurement of dual-lead ECG. Addition of the SpO2 module supports continuous and intermittent pulse oximetry measurement.

For information on Precautions or Accessories, refer to the appropriate portion in the front matter section of this manual.

The information in this section is subject to change without notice.

1.1.1 Warranty. The VISION TelePak is warranted against defects in materials and workmanship for twelve (12) months from date of shipment to original purchaser. Accessories such as cables and SpO2 sensors are warranted for one (1) year from date of shipment. Warranty is valid only to original buyer. Defective equipment should be returned freight prepaid to Invivo. Equipment returned with defective parts and assemblies will be either repaired or replaced. This warranty is not applicable if repair has been attempted, if the instrument has been damaged due to operation outside environmental and power specifications for product, or due to improper handling or use.

NOTE

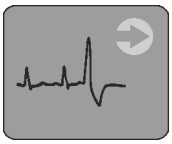
The foregoing warranty is in lieu of all other warranties expressed or implied, including but not limited to any implied warranty or merchantability, fitness or adequacy for any particular purpose or use. Invivo shall not be liable for any incidental or consequential damages.

1.1.2 Symbols. The following cautionary symbol appears on the VISION TelePak unit. Familiarize yourself with these symbols before using the VISION TelePak.

Symbol	Description
	Latex-free materials are used.
	Attention, consult accompanying documents.
	Defibrillator-proof type CF equipment (IEC 60601-1) protection against shock.
	Symbol for electrical safety (Canada and United States).

1.2 Operation of the VISION TelePak Transmitter. The VISION TelePak telemetry transmitter is intended for use by health care practitioners only. Observe all safety precautions, especially those that appear within this manual.

1.2.1 Control Keys. The VISION TelePak has three control keys that provide the operator with a method for changing the displayed waveform, activating the nurse call system, making a remote printout and navigation through the operational menu's.

Control Key	Description
	**Waveform Control Key.** The **Waveform** key provides the ability to select the displayed waveform. There are up to five (5) waveforms available: ECG Leads I, II, III and V, and (if available) SpO2. In addition, after display timeout, holding this key for three (3) seconds will re-activate the display and, in the configuration modes, this key advances the option selection. If Nurse Call is active, pressing this key clears the call.
	**Nurse Call Control Key.** Holding the **Nurse Call** key for 1 second will send a ***Call*** condition to the host and the message "**NURSE**" is shown on the display screen for as long as the call condition is active. The call condition remains active until cleared (by momentarily pressing the **Waveform** key) or the selected timeout expires. The timeout is user selectable with timeouts of 1, 2, 3, 4 and 5 minutes, latching and OFF. While in the configuration modes, this key is used to increment the setting or answer YES.
	**Remote Record Control Key.** Holding the **Remote Record** key for one (1) second will send a RECORD command to the receiving central station system. The message "**RECORD**" is shown on the display screen for two (2) seconds. While in the configuration modes, this key is used to decrement the setting or answer NO.

1.2.2 Display. Upon power up, the display screen shows the System Information page for two (2) seconds. This page contains the current channel selected and the software revision. After two (2) seconds the display switches to the Monitor page to display the selected waveform, lead conditions, battery condition and, if connected, the SpO2 information.

a. **Display On.** Once on, the display and backlight will remain on for 4.5 minutes if no keys are pressed (pressing any key restarts this timeout sequence); upon timeout the display and backlight turns off. To re-enable the display, press and hold the **Waveform** key for three (3) seconds. Holding the **Nurse Call** or **Remote Record** keys for three (3) seconds will momentarily enable the display to show messages.

b. **SpO2 Display.** The NONIN SpO2 module is auto detected upon plug in. When plugged in the display will reformat to accommodate the new data and, when the module is removed, the display reformats to remove the SpO2 data.

c. **Monitor Page.** The Monitor Page shows a waveform, lead conditions, battery condition and, if connected, SpO2 information.

(1) **Waveform Description.** Depending on lead connections, and whether the SpO2 module is connected, the waveform has up to five (5) possible choices: I, II, III, V and SpO2.

(a) To advance through the possible waveform choices, press the **Waveform** key.

(b) The selection is indicated in the upper left hand corner of the display screen.

(c) The Waveform trace is 1.3 seconds in duration with SpO2 data and 1.9 seconds without SpO2 data.

(d) If the waveform has failed the display screen will show dashes.

(e) To the left of the waveform there is a single vertical line that is equivalent to 1 mV in height. This line indicates the relative size of the waveform.

(f) There is no user control of waveform sizing. The size bar adjusts automatically as required. If the waveform peaks are above the display the system will size down and if no waveform appears in the upper 1/3 of the display then the system will size up.

(g) There is no size bar during SpO2 waveform display.

(h) The waveform is intended as an aid for lead placement only and is not suitable for diagnosis.

(2) **Lead Condition Indicators.** The Lead Condition indicators are bars that represent lead impedance.

(a) Each bar is 8 pixels in size with the lead designation on the left.

(b) A full bar represents low impedance (<500 kOhms).

(c) No bar represents high impedance (>2 MOhms).

(d) During a "NO" bar condition, the lead condition designator will flash at a one (1) second rate.

(e) When the 3-lead options is selected, the RL and C lead indicators are not displayed.

(3) **Battery Condition Indicator.** The Battery Condition indicator represents battery life. If the bar is at the Zero (0) level, then a "Battery Low" condition exists and the battery icon will flash.

(4) **SpO2 Information.** SpO2 information consists of the patients Oxygen Saturation value and Pulse Rate. This information will only appear when the NONIN module is detected.

1.2.3 Powering up the transmitter. The VISION TelePak will activate upon placement of two AA (alkaline) batteries into the battery compartment. Placement of the batteries automatically enables telemetry reception at the Vision Central Station or bedside monitor (if the transmitter channel is assigned at the receiving device).

a. **Activating the VISION TelePak.** Perform the following to install batteries and activate transmitter:

(1) Open battery compartment door on the VISION TelePak.

(2) Install batteries and close door.

(3) When batteries are installed, the LCD display on transmitter face will display current VISION TelePak channel number. This channel must be assigned to a patient window at the Central or to the Bedside monitor so communication can occur between devices.

(4) When battery life is depleted, **both** batteries must be changed.

1.2.4 Configuration Modes. There are two (2) configuration modes available on the VISION TelePak: BIO and NURSE. The BIO mode allows configuration of all the available options while the NURSE mode allows configuration of a subset of the BIO options. The **Waveform** key cycles through the options while the **Nurse Call/Remote Record** keys increment/decrement through the settings. A single press advances the selection by one (1) while holding the key will auto increment/decrement the selection.

a. **BIO Mode.** To enter the BIO Mode, hold the **Waveform** key during power up of the VISION TelePak. The display will come up with the BIO Configuration page.

(1) Available BIO Configuration settings are: Channel ID, Language, LCD Intensity, SpO2 Avg., SpO2 Mode, Nurse Call Timeout, Remote Record Enable, 3- or 5-Lead Selection and 3-Lead Default.

(a) **SELECT CHANL.** This selects the channel ID for connection to the Vision Central Station or bedside monitor.

(b) **LANGUAGE.** The only language supported at this time is English.

(c) **LCD BIAS.** This value will adjust the LCD contrast setting with an available range of 0 - 31. The default is 15.

(d) **NURSE.** This selects the duration of the Nurse Call timeout. Once initiated, the Nurse Call will remain active until manually cleared (by pressing the **Waveform** key) or until the selected timeout value has elapsed. The available timeout values are 1 (minute), 2 (minutes), 3 (minutes), 4 (minutes), 5 (minutes), LATCHING and OFF. The default is 1 minute.

(e) **RECORD.** This selection will enable/disable the remote record function. The default is ON (enabled).

(2) Advance through the available options by pressing the **Waveform** key.

(3) To change the settings use the **Nurse Call** key to Increment through the options or answer YES and the **Remote Record** key to Decrement through the options or answer NO.

(4) Once all the configuration settings have been scrolled through, the SAVE/ EXIT query will appear. If no changes were made only the EXIT query appears. To save the changes answer YES to SAVE, to discard the changes answer NO.

b. **NURSE Mode.** To enter the NURSE Mode, place the VISION TelePak in normal mode of operation with the display screen ON then hold down both the **Nurse Call** and **Remote Record** keys for three (3) seconds. The display will change to the first Nurse Configuration page.

(1) Available NURSE Configuration settings are: SpO2 Mode, SpO2 Avg., 3- or 5-Lead Selection and 3-Lead Default.

(a) **O2 MODE.** This selects the O2 interval time. Available selections are 1 minute, 2 minute or OFF (continuous). The Default setting os OFF (continuous).

(b) **O2 AVG.** This selects SAT/PR value averaging. The available selections are SLOW (8 seconds) and NORMAL (4 seconds). The default is NORMAL

(c) **LEAD MODE.** This sets lead configuration to 3-lead or 5-lead mode. The default is 5-lead.

(d) **3LD SELECT.** This selects the 3-lead configuration. Only I and II are available. The default is II.

(2) Advance through the available settings by pressing the **Waveform** key.

(3) To change the settings use the **Nurse Call** key to Increment through the options or answer YES and the **Remote Record** key to Decrement through the options or answer NO.

(4) Once all the configuration settings have been scrolled through, the SAVE/ EXIT query will appear. If no changes were made only the EXIT query appears. To save the changes answer YES to SAVE, to discard the changes answer NO.

1.2.5 SpO2 Operation. The NONIN SpO2 module is automatically detected when plugged in with the display screen reconfiguring for the SpO2 data.

a. **SpO2 Modes of Operation.** There are two (2) modes of operation available: Continuous and Interval.

(1) **Continuous Mode of Operation.** This mode provides continuous SpO2 readings and waveform data. If no valid readings are obtained, the values are set to "---" to indicate that they are invalid.

(2) **Interval Mode of Operation.** This mode extends battery life by momentarily sampling SpO2 readings and waveform data by turning the SpO2 module on and off. When in Interval Mode with the module off, the SpO2 data is placed in a reverse video window to indicate that the data is not current. Normal video means data updates are active (current). If no valid readings are obtained, the values are set to "---" to indicate that they are invalid. The interval active period is extended until a valid reading is obtained.

b. **SpO2 Average.** This option selects the Saturation and Pulse Rate averaging time. The SLOW selection averages over a period of eight (8) seconds. The NORMAL selection averages of a period of four (4) seconds.

1.3 ECG Monitoring. It is recommended that proper elecrode site preparation be completed prior to placement of electrodes on the patient. It is further recommended that only electrodes conforming to ANSI/AAMI EC12 are selected and applied to the patient for use with this telemetry system. Please see the back of the transmitter for a lead placement chart asneeded. In the configurations mode (**See Section 1.2.4**) select either 3 lead or 5 lead ECG monitoring as appropriate for this patient. The back-lit display on this transmitter shuld be used as a guide to achieve good ECG signal quality (**See Section 1.2.2**, 1(a) through (d) waveform description and 2(a) through (e) lead indicators).

1.4 SpO2 Monitoring. Place the VISION TelePak transmitter into the SpO2 mode simply by attaching the XPod patient cable and 8000A Clip Finger Sensor (or IPod SpO2 sensor) cable to the transmitter. The SpO2 sensor is auto detected when connected to the transmitter tush turning on the SpO2 parameter automatically. Attach the sensor to the patient appropriately and SpO2 monitoring will commence. **See Section 1.2.4** to configure O2 MODE and O2 AVG.

1.5 Recording. Holding the **Remote Record** key for one (1) second will send a RECORD command to the receiver. The message "**RECORD**" is shown on the display screen for two (2) seconds.

1.6 Nurse Call. Holding the **Nurse Call** key for one (1) second sends a ***Call*** condition to the host and the message "**NURSE**" is shown on the display screen for as long as the call condition is active. The call condition remains active until cleared (by momentarily pressing the **Waveform** key) or the selected timeout expires. The timeout is user selectable with timeouts of 1, 2, 3, 4 and 5 minutes, latching and OFF.

1.7 Powering Down the VISION TelePak. Before powering down the VISION TelePak, ensure that all leads and cables have been removed from the patient. The power will remain on as long as the batteries are in the battery compartment; for long term storage or non-use, remove both batteries from the VISION TelePak.

a. **Turning off the VISION TelePak at the Vision Central Station.** After powering down the VISION TelePak, the receiver must be TURNED OFF at the Vision Central Station to halt lead alarms and display. Perform the following to discontinue VISION TelePak monitoring at the Vision:

(1) Touch (or click) the appropriate patient window.

(2) When ECG window display appears on the lower screen touch (or click the Transmitter tab.

(3) Touch (or click) OFF.

1.8 Cleaning. The following guidelines provide information on cleaning the VISION TelePak:

a. For cleaning, use only a lint-free, nonabrasive cloth which has been slightly dampened with mild detergent, a glass cleaner, or a non-alcoholic based solvent.

b. Avoid harsh cleaning solutions such as isopropyl alcohol or other solvents that might harm plastic surfaces. Avoid anti-bacterial cleaning solutions, especially those containing Phenol.

c. Do not immerse unit or any components in liquid.

d. Do not spray liquids directly on the VISION TelePak.

e. Do not allow liquids to penetrate the VISION TelePak connectors or case.

APPENDIX A
SPECIFICATIONS

GENERAL	
Patient Safety	
Designed to meet the requirements of CSA, UL 2601 and IEC 601-1. Transmitter complies with radio frequency exposure limits specified in FCC sections 1.1307 and 2.1093.	
Water resistant.	
Defibrillator protection up to 5 KV.	
Power Requirements	
Operating Voltage	3 V.
Battery Type	Two (2) 1.5V AA batteries, alkaline.
Battery Operation Time	36 hours with continuous SpO2, minimum. 72 hours with ECG only, minimum.
Environment	
Operating Temperature	+10° C to 40° C
Storage Temperature	-40° C to 70° C
Operating Relative Humidity	30% to 75%
Storage Relative Humidity	10% to 100%
Dimensions	
Height	13.2 cm (5.2 inches).
Width	7.4 cm (2.9 inches).
Depth	2.54 cm (1.0 inch).
Weight	127.5 g (4.5 ounces) without batteries.
Remote Communication	
FCC Certification	EHC20701
Rated RF Output Power	5 dBm
Frequency Range	WMTS transmit band (608-614mhz).
Number of Channels	12.5 kHz frequency resolution with the ability to operate at 75 kHz channel separations.
Display	
Type	LCD monochrome display with backlight.
Screen Size	3.8 x 1.3 cm (1.5 x 0.5 inches).
Sweep Speed	20 mm/sec
Waveform Display Height	7.5 mm

ECG CHANNEL	
ECG Amplifier	
Over voltage Protection	Protected against defibrillator and electro surgery potentials.
Standard Lead Configurations	I, II or III and V.
Differential Input Impedance	20 Meg.
Common Mode Rejection Ratio	>80 dB.
Electrode Offset Potential	+/- 300 mV.
Baseline Recover from defibrillation	<3 seconds.
Alarms	
Set at the Remote Monitor.	

PULSE OXIMETER	
SpO2 port standard for NONIN external SpO2 sensor module.	
Continuous or Interval (1 or 2 minutes as selected)) mode operation	
Saturation Range	70 to 100% (functional).
Saturation Accuracy	Adult/Pediatric +/- 3.
Pulse Range	18 to 255 bpm.
Pulse Accuracy	Adult/Pediatric: +/- 3 bpm.
Pulse Waveform	Plethysmograph of vascular bed
Alarm Limits	
Set at the Remote Monitor	

NOTES