TECHNICAL INFORMATION FOR THE TYPE ACCEPTANCE SUBMISSION OF MODEL 90343 DIGITAL TELEMETRY MULTI-PARAMETER TRANSMITTER TO THE FEDERAL COMMUNICATIONS COMMISSION: FCC ID: CM676A90343

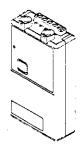
EXHIBIT 15 - Operators Manual Draft

Enclosed is the Operators Manual draft. Also included are the preliminary Data Sheet and below, a preliminary draft of the table of contents of the planned Service Manual. The Service Manual will be completed before any units are delivered to end-users. A copy of the completed Service Manual will be furnished to the FCC as soon as it is available.

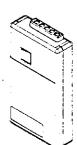
PROPOSED TABLE OF CONTENTS FOR SERVICE MANUAL

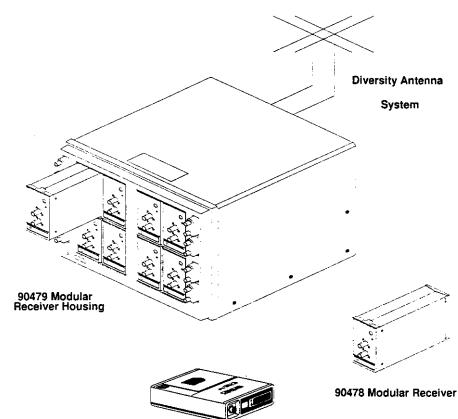
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90343 Digital Telemetry Multi-parameter Transmitter 90347 Digital Telemetry ECG Transmitter





90217 ABP Monitor

Ultraview Digital Telemetry 90343, 90347, 90478

- Touchscreen control of all module functions and compatible with all Ultraview Care Network[™] and PCMS[™] monitors
- Lightweight, water resistant transmitter
- Diversity antenna system
- Tunable modular receivers
- Modular receiver converts bedside monitors to telemetry operation
- Works with portable monitor for transport of telemetry monitored patients
- Multi-lead ECG with ST segment analysis option; comprehensive arrhythmia and ST trending
- Multi-Parameter telemetry monitoring ECG, SpO₂, and NIBP (optional)
- Usable in bedside, ambulatory, and cardiac rehabilitation environments within the medical center
- Module Configuration Manager enables the hospital to customize the receiver's patient monitoring functions to specific patient populations, clinical protocols, or operating preferences
- Graded alarm functions enables the hospital to define different alarm tones (high, medium, low) according to event severity (critical, warning, advisory)

SPECIFICATIONS

TRANSMITTER (90343, 90347)

ECG Transmission — 4 leads (90343, 90347) synchronized RF digital signal

Multi-Parameter Transmission (90343) — SpO₂ (saturation, SpO₂ sensor status) and optional NIBP (systolic, diastolic, mean pressure, pulse rate, measurement time tag, alarm conditions) via the model 90217 ABP monitor

Additional Data Transmitted — Patient record, low battery indicator, pacer flag, patient ID code, and electrode connection status

Electrode Configuration — Individually replaceable DIN standard safety lead wires

Output Power - 2mW ERP, typical

Water Resistance — Meets EN60529 IPX2

External Indicator — Yellow LED flashes when battery level is low

Battery — 9V battery; see Table 1 for battery life expectancy

ultraview **Digital** Telemetry 90343, 90347,

SPECIFICATIONS

TRANSMITTER PHYSICAL DIMENSIONS

90343 (Multi-Parameter)

Height: 5.25 in (13.3 cm) Width: 2.85 in (7.2 cm)1.18 in Depth: (2.9 cm) Weight (w/out battery): 7.4 oz (210.2 gm)

90347 (ECG-only)

Height: 5.25 in (13.3 cm) Width: 2.85 in (7.2 cm) Depth: 0.98 in (2.5 cm) Weight (w/out battery): 5.6 oz (159.0 gm)

ECG

Maximum Input — ±5 mV (±10%)

DC Offset — Up to ±300 mV, with no more than 2% signal amplitude degradation

Overdrive Recovery Time --- < 1 second circuit settling time with offset voltage < 500 mV

Noise — $< 30\mu V$ p-p, rti, at 30Hz bandwidth

CMRR --- > 85dB (Monitor Mode)

QRS Detection — Detects QRS complexes with amplitudes of 0.5 to 5.0 mV (adult) or 0.15 to 5.0 mV (neonatal)

Defibrillator Protection — Meets IEC 601-2-27, AAMI EC-13

Overdrive Recovery --- < 1 second circuit settling time with offset < 500mV

Resolution — 2.5 µV per LSB, rti

Input Impedance — > $10M\Omega$ minimum differential @ 10Hz

Gain Accuracy — ±5 %

Pacer Rejection - Baseline shift < 0.2 mV (measured at ECG x 1,000 output)

Pacer Detection — Detects pacer pulses of ±2 mV to ±700 mV with pulse widths of 0.2 to 2 msec and rise times 10% of width not to exceed 100 usec

Signal Bandwidth — 0.05 to 30 Hz ±10% (-3dB) Sample Rate — 120 samples per second

SpO₂

SpO₂ Sensor Interface —

Red LED drive (max.): 200 mA peak @ 6.25% duty cycle IR LED drive (max.): 200 mA peak @ 6.25% duty cycle

SpO₂ Measurement Method — Functional saturation (oxygen saturation of functional hemoglobin)

SpO₂ Measurement Method —

Continuous; Episodic (1 minute, 2 minutes, and 5 minutes) sampling intervals; factory default setting is 2 minute episodic sampling interval

MODULAR RECEIVER (90478)

Module includes:

Module Configuration Manager capability (refer to the Module Configuration Manager chapter of the PCMS Operations Manual for complete feature specifications)

ECG Trends — (with appropriate mainframe option) 24 hours of trended data can be displayed in 1.5-, 3-, 6-, 12-, or 24-hour segments; data is stored in 1-minute resolution

High Level Analog Output -

ECG 1: Used for defibrillator synchronization Dynamic Range: ±5mV (±10%), rti Gain: ECG x 1000 (±5%)

Bandwidth: 0.05 to 30 Hz ±10% (-3dB)

Module Parameter count — This module counts as 1 or 2 parameters when computing parameter capacity for monitors 1 displayed ECG lead = 1 parameter 2 displayed ECG leads = 2 parameters

Options — The following ECG processing options are available in the 90478

A — Basic ECG Alarms for high and low heart rate, asystole and ventricular fibrillation

B — MultiView ™ I — Enables users to review trends of abnormals per minute; provides additional alarms for abnormals per minute and abnormals in a row

C — MultiView II — Enables users to review the dominant morphology as well as episodes or classes of ventricular fibrillation, ventricular tachycardia (runs), couplets, single abnormals, tachycardia, pauses, ventricular and atrio-ventricular pacing; provides additional alarms for abnormals in a row, abnormals per minute, and tachycardia

S — ST segment analysis/review/trend X — Band operation

ECG Display

Heart Rate Range — 30 to 300 bpm; heart rates >300 bpm are displayed as "+++"

Heart Rate Alarm Limits — High: 5 to 300 bpm, Low: 0 to 200 bom; alarms automatically enabled over a range of 40 (adult) or 100 (neonatal) to 300 bpm

Accuracy — ±1% or 2 beats per minute (whichever is greater)

Numeric Update Rate — Every 3 seconds or immediately at the onset of an alarm

Trace Sweep Speeds — 50, 25, 12.5 mm/sec

ST Segment Analysis

Resolution — 0.08 mm

Range — 9mm (1 mV = 10 mm)

Leads — ST Segment Analysis continously performed on up to 7 leads

SPECIFICATIONS

Alarms - Single lead or multiple leads; individual leads can be deselected

Trends - Up to 24 hours of trend data can be displayed in 1.5-, 3-, 6-, 12-, or 24-hour time tracks

SpO₂ Display

Measurement Range — 30 to 100% O₂ Saturation

Saturation Accuracy: — Sensor Dependent

Saturation Resolution — ±1%

Pulse Rate Range - 30 to 250 bpm

Pulse Rate Accuracy — ±3 bpm

Alarms - High and low saturation values; factory default limits are: high, 100%; low 85%

> High range: 31% to 100% Low range: 30% to 99%

Display Update -- Every 2 seconds for continuous SpO2 readings

NIBP Display

(See specifications for the 90217 ABP Monitor)

Measurement Range (adult only) ---

Systolic: 8.0 to 35.0 kPa (60 to 260 mmHg) Diastolic: 9.0 to 27.0 kPa (30 to 200 mmHg) Mean: 5.3 to 31.0 kPa (40 to 230 mmHg)

Pulse Rate Range --- 40 to 180 bpm

Pressure Accuracy — ±2% or ±3 mmHg

(whichever is greater) Resolution — 1mmHg

Time Between Readings — selectable, >6 to 120 minutes

Alarms — High and low alarms for all measured parameters

> High range: 8.0 to 35.0 kPa (60 to 260 mmHg)

Low range: 4.0 to 27.0 kPa

(30 to 200 mmHg)

RECEIVER ELECTRICAL REQUIREMENTS

Power Consumption — ≤ 5.0 watts External Indicators — LED lights when user

accesses control

RECEIVER PHYSICAL DIMENSIONS

Heiaht:

4.46 in (11.32 cm)

Width:

2.24 in (5.68 cm)

Depth:

7.00 in (17.78 cm)

Weiaht:

2.4 lbs (1.11 kg)

RECEIVER HOUSING (90479)

Accommodates up to 8 modular receivers

PHYSICAL DIMENSIONS (HOUSING)

Height:

12.0 in (30.5 cm)

Width:

(34.3 cm) 13.5 in

Depth:

(44.5 cm) (includes protective cover)

Weight:

32.0 lbs (14.6 kg)

(without modules loaded)

POWER REQUIREMENTS

17.5 in

100-120 VAC, 50/60Hz, 2A; 220-240 VAC, 50/60Hz, 1A

ENVIRONMENTAL REQUIREMENTS

Operating -

Humidity: Altitude:

Temperature: 50° to 104° F (10° to 40° C) 10% to 95% (non-condensing)

0 to 10,000 ft (0 to 3,030.3 m)

Storage ---

Humidity:

Temperature: --40° to 149° F (-40° to 75° C) 10% to 100% (non-condensing)

Altitude:

-500 to 40,000 ft (-151.5 to

12,121.2 m)

REGULATORY APPROVALS

All models are ETL listed and meet UL2601-1 standard for electrical safety; approved by

CSA

Models 90343, 90347, 90478, and 90479 approved by FCC and DOC, and are CE marked in accordance with the Medical Device Directive 93/42/EEC

ACCESSORIES

90343 Transmitter Pouch

Part Number: 015-0500-00

90347 Transmitter Pouch

Part Number: 016-0188-00

9V Alkaline Battery

Part Number: 146-0033-00

9v Lithium Battery

Part Number: 146-0054-00

DIN Standard Safety Lead Wire Set --- 5 wire

Part Number: 012-0285-01 Receiver Housing Protective Cover Part Number: 200-0180-00

Whip Antenna (VHF)

Part Number: 117-0035-00

Part Number: 344-0020-00

SpO₂ Adapter Cable (Spacelabs Medical)

Part Number: 012-589-00 SpO₂ Adapter Cable (Nellor) Part Number: 012-587-00

Ultraview Digital Telemetry 90343, 90347,

ultraview Digital Telemetry 90343, 90347, 90478

Spacelabs Medical, Inc. 15220 N.E. 40th Street P.O. Box 97013 Redmond, WA 98073-9713 (425) 882-3700

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All specifications are subject to change without notice.

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061-0801-00 Rev. A 08/98

SPECIFICATIONS

ABP Adapter Cable

Part Number: 012-588-00

ABP Pouch

Part Number: 015-501-00

SPACELABS MEDICAL SpO₂ SENSORS ACCURACY AND SENSOR SELECTIONS

Sensor Accuracy — Each sensor at ± one standard deviation:

80-100% ±2% absolute saturation 60-79% ±3% absolute saturation

0 - 59% not specified

Sensor Selections —

NELLCOR SpO₂ SENSOR ACCURACY AND SENSOR SELECTIONS

Nellcor Reusable SpO₂ Sensors —

Finger Clip (DS-100A) (P/N 690-0003-00) 70-100%, ±3% absolute saturation

OXIBAND A/N (OXI-A/N) (P/N 690-0004-00) 70-100%, ±3% absolute saturation OXIBAND P/I (OXI-P/I) (P/N 690-0039-00) 70-100%, ±3% absolute saturation

Nellcor Disposable SpO₂ Sensors —

Neonatal (N-25) (P/N 690-0006-00) 70-100% ±2.5% absolute saturation Pediatric (D-20) (P/N 690-0007-00) 70-100% ±2% absolute saturation Adult (D-25) (P/N 690-0001-00) 50-69% ±3% absolute saturation 70-100% ±2% absolute saturation Nasal (R-15) (P/N 690-0005-00) 80-100% ±3.5% absolute saturation

Table 1: Transmitter Battery Service Life¹ (hours)

Battery Type	9 Volt Aikaline					9 Volt Lithium				
Load Con- ditions ²	ECG Only	ECG and Con- tinuous SpO ₂	ECG and 1 minute Episodic SpO ₂	ECG and 2 minute Episodic SpO ₂	ECG and 5 minute Episodic SpO ₂ and NIBP	ECG Only	ECG and Con- tinuous SpO ₂	ECG and 1 minute Episodic SpO ₂	ECG and 2 minute Episodic SpO ₂	ECG and 5 minute Episodic SpO ₂
Model 90343	72	15	30	40	50	120	35	65	90	10
Model 90347	72	Not Applicable	Not Applicable	Not Applicable	Not Applicable	120	Not Applicable	Not Applicable	Not Applicable	Not Applicable

Operational service life in hours assuming a freshly charged battery used until the local "low battery" indicator begins to flash.

NIBP operations from a 90217 ABP Monitor sending readings to the 90343 Multi-parameter telemetry transmitter. The 90127 ABP Monitor will inflate standard a size adult cuff at least 240 times with alkaline batteries.

Directory MONITOR SETUP MONITOR RECORDER ADMIT/ MONITOR SCREEN TONES SETUP DISCH. CONFIG. **FORMAT** CONFIG. RECORDER CONFIGURATION (see Printing) RECORDING ALARM Select DURATION PARAMS waveform MONITOR CONFIGURATIONS zone BRIGHT TIME/ COLOR select bed NESS DATE CONFIG (or subnet, then bed) ADMIT/DISCHARGE - Select Function (see Admit/Discharge) select bed (or subnet, then bed) CHANGE ADMIT CHARGE DATA MONITOR SETUP Select type of tone to change (see Alarms) SUSPEND REMOTE ALARM PRINT REVIEW RELEARN **ALARMS** WATCH TONE PROCESSING ECG ON OFF ECG MENU - (Multi-Lead) (MultiView™ II option with Arrhythmia and Review ON - used with 90343/90347 transmitter) ECG ALARM LEAD CHANNEL SUSPEND FCG PRINT REVIEW SIZE **SETUP** FORMAT PROCESSING RELEARN LIMITS SELECT **ECG - RELEARN** CLEAR SAVE MEMORY MEMORY **ECG - CHANNEL FORMAT** 2nd LEAD 90343 only SpO2 SpO2 ON OFF (RATE) ON OFF AUTO SINGLE LEAD ALARM LEAD SWITCH 1st LEAD 2nd LEAD ON OFF ON OFF Bedside monitors only **FCG - SETUP** MONITOR PACED RATE SWEEP ORS CONFIG YES NO SETUP SPEED TONE EXTENDED SOURCE Redside Central ECG - TM SETUP only only PT RECORD LO BAT ASSIGN SET TM TM BED CHAN YES NO ON OFF Enable alternate rate source(s) ART SPO2 ECG ART SPO2 ON OFF ON OFF ON OFF ON OFF ECG - CONFIG ADULT ARR INFANT ON OFF MEAN NIBP ALM HI= DIA ON OFF XXX SPO2 ALM MSG ALM HI≖ LO= ALM DELAY ON OFF XXX **DELAY XXs** ECG ALM ABN PER ST LIM ABN IN ON OFF MIN=XX

Based on the features of your monitor and options purchased, more (or less) keys may appear here than on

your menu screens.

NOTE

ULTRAVIEW DIGITAL TELEMETRY-1

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General Telemetry Overview

The digital telemetry receiver module (Model 90478) when used in conjunction with Spacelabs Medical telemetry transmitters, PCMS[™] or Ultraview[™] monitor, and modular receiver housing (Model 90479), provides continuous monitoring of electrocardiographic signals in order to detect abnormal cardiac rhythms, including life-threatening arrhythmias such as asystole, ventricular fibrillation, and ventricular tachycardia. In addition, when used with the digital telemetry multi-parameter transmitter (model 90343), monitoring of electrocardiographic signals is augmented by the availability of continuous or episodic SpO₂ measurements and episodic NIBP measurements.



- The transmitters and receivers referred to in this chapter comply 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.
- Changes or modifications not expressly approved by Spacelabs Medical will void the user's authority to operate the equipment.

Transmitters

The transmitter is a small battery-powered device carried by the patient to monitor ECG activity and SpO₂/NIBP (90343 only) data, and transmit this information to the telemetry receiver module.

- The 90343 and 90347 transmit four leads of ECG and use up to five lead wires.
 However, only two leads may be displayed simultaneously.
- The 90343 is also capable of transmitting numerical NIBP and SpO₂ data. This
 data is displayed simultaneously with that of the ECG waveform data.

Up to five standard disposable silver/silver chloride chest electrodes are connected to the patient: the ECG lead wires are attached to these electrodes and are connected to the transmitter. A patient-operated RECORD button initiates an ECG strip at the system printer if this feature is enabled at the central or bedside.



- This device has a limited bandwidth from .05 to 30 Hz, which may adversely affect the recording of high frequency components in the ECG signal, especially when the morphology of the ECG changes rapidly.
- This device has a limited dynamic range of ± 5mV, which may render the device vulnerable to saturation by ECG signals with amplitudes higher than 5mV.
- To clean the transmitter use only the following solutions per the manufacturer's labeling: Isopropyl Alcohol (70%), Hydrogen Peroxide, Cidex, Betadine, and Clorox. Use of cleaning solutions other than those listed will VOID the warranty of the digital telemetry transmitter cases.



Clean the transmitter after each use. The transmitter does not require any preventative maintenance other than cleaning.

Transmitter Batteries

A 9-Volt alkaline battery (P/N 146-0033-00) is recommended for standard use in the digital telemetry transmitter. A 9-Volt lithium battery (P/N 146-0054-00) may also be used for applications requiring more extended battery service life.

Always observe the battery position and polarity as illustrated at the bottom of the battery compartment. After battery installation, close and latch the compartment cover. The transmitter begins transmitting as soon as the battery is in place.



- Whenever the transmitter is not in use, the battery should be removed. Insert a battery only when the transmitter is actually being used with a patient.
- The LOW BATTERY message appears and an alarm tone sounds (if LO BAT is set to ON) when the transmitter battery voltage falls below 7.0 volts. When this message appears, the transmitter has up to 1 hour (depending on transmitter type and selected options) of operating time left, depending on the type of battery used. The low battery indicator will flash on the enhanced digital telemetry transmitters when the transmitter battery voltage falls below 7.0 Volts.

PCMS

Digital Telemetry Receiver Module

The telemetry receiver module plugs into a bedside, central, or transport monitor, or a digital telemetry module housing. The receiver module receives patient vital sign data from the transmitter. This data is reconstructed by the receiver module, displayed on the monitor and analyzed as described in the *ECG*, *Arrhythmia*, and *ST Analysis* chapters, and in the various SpO₂ and NIBP sections of this chapter.



- Telemetry systems may be more susceptible to interference than hardwired systems, which may impact patient safety.
- Operation of hand-held, wireless telephone equipment (for example, cordless telephones, cellular telephones, etc.) near telemetry systems may cause interference and should be discouraged.
- Do not install a telemetry receiver module into a bedside which is currently equipped with any other ECG module, hardwired or telemetry, (or SpO₂ module or NIBP module if the 90343 is operating with that specific receiver module).
 Doing so may result in inaccurate patient data displays at remote monitors.

Digital Telemetry Module Housing

The telemetry module housing can hold up to eight separate telemetry receiver modules. Except for the ON/OFF switches, there are no operator controls on the module housing. For normal operation with AC mains power applied, the AC mains indicator light on the front panel of the housing must be illuminated. Operation of the system without AC mains power is limited to ten minutes of battery backup time.

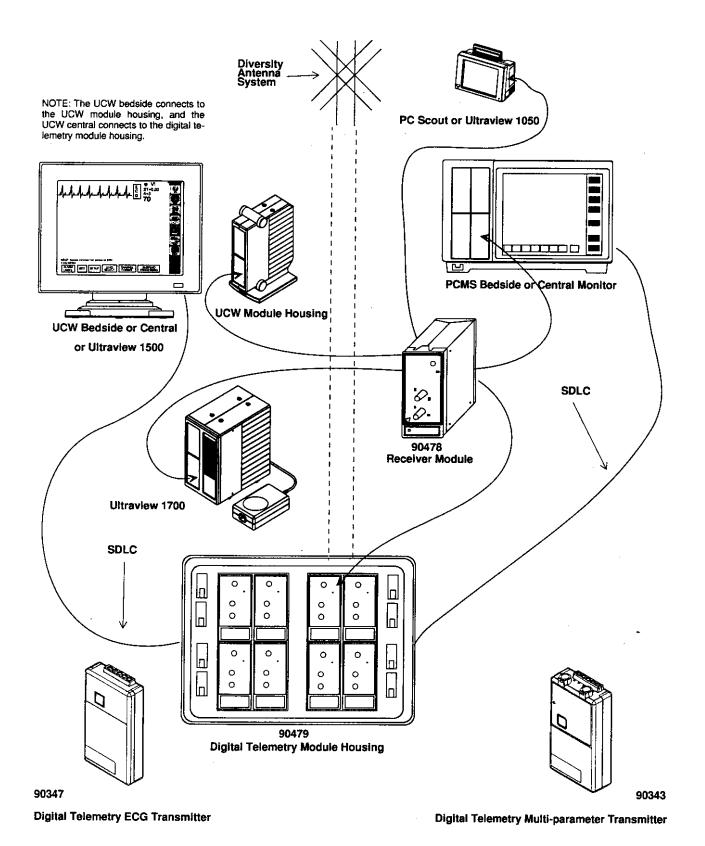


Figure Telemetry-1: Ultraview Digital Telemetry System

To set up the central for ECG (if bed name not remembered):

 Touch key label that matches transmitter's frequency

"我们就没一只要你的我们还没有了一个。"

2 Select bed/room number for transmitter channel

To set up the central for ECG (PC1 only):

- 1 Touch MONITOR SETUP
- 2 Touch SCREEN FORMAT
- 3 Select zone desired
- 4 Select bed/room number
- 5 Select ECG ON

To tune a receiver module at bedside:

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- 1 Touch ECG
- 2 Touch SETUP
- 3 Touch TM SETUP
- 4 Touch SET TM CHANNEL
- 5 Select the digit to change. Use the ↑↓ keys to select the value for that digit.
- 6 Repeat for all digits as necessary
- 7 Touch STORE

To admit a patient:

- 1 Touch MONITOR SETUP
- 2 Touch ADMIT/DISCH
- 3 Select bed/room number for channel
- 4 Touch ADMIT
- 5 Select YES
- 6 Select ID, NAME, HEIGHT, WEIGHT, or BSA
- 7 Enter data using pop-up keypad or keyboard
- 8 Touch ENTER
- 9 Repeat steps 6 8 until all data has been entered

Assigning a Telemetry Channel

Telemetry transmitters are preassigned with channel frequencies. This channel number is identified on the back of the case and cannot be changed. To receive this telemetry channel, one of the receivers in the telemetry receiver housing must be tuned to its assigned frequency.



- Tuning telemetry receiver modules to transmitter channels at the central must be done by a qualified service person.
- Your central can be configured to remember beds that are assigned to individual telemetry channels using the Module Configuration Manager feature. These beds are permanently assigned until you deassign or reassign them.

Tuning a Receiver for a Bedside

The central must be tuned by a qualified service person, but the bedside may be tuned using the ECG TM Setup menu. You may use this menu to tune the receiver module to the pre-assigned channel frequencies on the telemetry transmitter.



The module default is set for North America — UHF band operation. If operating in another country you must select the appropriate frequency band using the Module Configuration Manager feature.

Entering Patient Information

The ADMIT/DISCHARGE menu enables you to enter a patient identification (ID) number, name, height, weight, and body surface area (BSA).



Admitting a new patient purges data from the previous patient on that telemetry channel.

Acknowledging Signal Loss

When a telemetry signal is lost because the transmitter is out of range or the battery is removed, the receiver initiates a squelch condition. This condition is indicated when a triangular waveform replaces the normal ECG waveform. The notation SQUELCH is included in the edge print for any strip chart recording. The ECG trace automatically begins again if the lost signal returns.

After eight seconds of loss, the IS SIGNAL LOSS PERMANENT? message appears. Selecting NO suspends alarm tones. Selecting YES displays the message DISCHARGE THE PATIENT? Selecting YES again, provides you with the message PURGES DATA-ARE YOU SURE? Selecting YES a third time, discharges the patient from the system and purges all data for that patient. Selecting NO at any point in this sequence returns you to the previous option.

Setting Battery Status Alarms

The telemetry battery alarm tone alerts you to a low battery condition in the transmitter. A LOW BATTERY message also appears in the ECG zone involved. You may select to disable the low battery alarm tone, if your bedside or central is configured to do so.

The factory default setting for low battery alarm is ON.

Controlling Patient-Initiated Recordings

If the Patient Record function is activated (PT RECORD is YES) in the ECG TM SETUP menu, the patient may initiate a recording by pressing the RECORD button on the front of the transmitter.

Digital Telemetry Problem Solving

INTERMITTENT SIGNAL LOSS

This message indicates that the patient may be out of antenna range, or that the battery depleted.

- Return the patient into antenna range.
- Check that the battery is functioning properly.

LOW BATTERY

The battery is weak. After this message appears, the battery has from a few hours to 24 hours of charge left (depending on the type of battery used). Install new battery.

SIGNAL INTERFERENCE

This message indicates, via the displayed triangle squelch waveform, that a stronger, interferring, signal has been detected.

PERMANENT SIGNAL LOSS

This message indicates that no RF signal is being detected.

To control low battery alarms:

- 1 Touch ECG
- 2 Touch SETUP
- 3 Touch TM SETUP
- 4 Select LO BAT ON or OFF

To control transmitter's Patient Record function:

- 1 Touch ECG
- 2 Touch SETUP
- 3 Touch TM SETUP
- 4 Select PT RECORD YES or NO

To initiate ECG monitoring:

- 1 Select a transmitter
- 2 Note its channel number
- 3 Attach lead wires to transmitter

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- 4 Attach lead wires to electrodes
- 5 Install a transmitter battery
- Apply electrodes to patient
- 7 Close the transmitter case

Setting Up ECG Monitoring

Each lead wire must be plugged into the transmitter, connected to an electrode, and then attached to the patient. Match the lead wire color to the color-coded connectors on the top of the transmitter case. Refer to the *ECG* chapter in this manual for details regarding electrode application. Telemetry patients are commonly ambulatory and require optimal skin preparation and lead application to minimize motion artifact. After the electrodes and lead wires have been attached, it is important to tape a loop of lead wire close to the electrode to minimize stress or pulling on the electrode itself - a process called stress-looping.

ECG monitoring begins when the telemetry receiver module detects a signal sent by a telemetry transmitter. The telemetry transmitter sends a signal as soon as its battery is installed.

ECG telemetry reception requires the following minimum conditions:

- The telemetry receiver module must be connected to a PCMS or Ultraview monitor, either directly or through a module housing, with the power ON and a Spacelabs Medical diversity antenna connected.
- ECG electrodes must be properly attached to the patient, and lead wires to the transmitter.
- The transmitter battery must be functional.
- The telemetry receiver module must be tuned to the telemetry transmitter's frequency (channel number).



- All system connections must be made by Spacelabs Medical personnel only.
- Leakage currents are not affected by the high level output. The patient is electrically isolated from the patient monitor by the RF link.



- Operation of television receivers or other CRT displays near the transmitter (within 2 to 3 feet), or operation of some pacemaker programmers may suppress the ECG waveform, preventing QRS detection and rate counting. An erroneous Asystole alarm may result.
- Signals resulting from devices such as Automatic Implantable Cardiac Defibrillators (AICD) may momentarily blank the ECG trace rather than display an out-of-range signal. In such cases, it may not be apparent that the AICD has fired and the condition of the patient should be checked. In all instances of AICD firing, the bedside or central will redisplay the ECG waveform within 5 seconds.

ECG monitoring in telemetry is identical to hardwired ECG monitoring. Refer to the ECG, Arrhythmia, and ST Analysis chapters of the *PCMS Operations Manual* (P/N 070-1001-xx) for detailed descriptions of configurations, displays, and controls. A brief overview of ECG monitoring follows.

Electrodes

Use silver/silver-chloride electrodes or their equivalent. Always connect all electrodes required for a particular lead. Missing electrodes may result in the loss of ECG tracing. Refer to the ECG chapter for information on placing the electrodes.



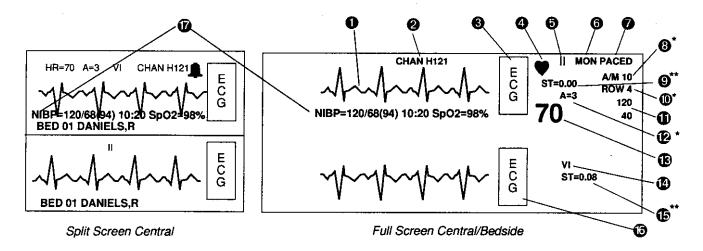
Use only Spacelabs Medical recommended electrodes. Some electrodes may be subject to large offset potentials due to polarization. Recovery time after application of defibrillator pulses may be especially compromised. Squeeze bulb electrodes commonly used for diagnostic ECG recording may be particularly vulnerable to this effect.



- Visually inspect each lead wire for obvious damage and replace as needed.
- Only use patient cables and lead wires specified by Spacelabs Medical. Other cables and lead wires may degrade performance and may damage the monitor during defibrillation or high frequency electrosurgery. Non-Spacelabs Medical cables and lead wires may also change the required input impedance and D.C. offset voltage, affecting monitor performance.
- · Do not use stainless steel electrodes.
- Do not allow conductive parts of electrodes and connectors, including the reference electrode, to contact other conductive parts, including the ground.
- Poor cable dress or improper electrode preparation may cause line isolation monitor transients to resemble actual cardiac waveforms and thus inhibit heart rate alarms. Refer to the ECG chapter in this manual for details on proper electrode preparation and application.

Display Detail

Signal detection is indicated on your monitor when an ECG signal appears next to the ECG parameter key in the zone assigned to receive the transmitted telemetry channel. The transmitter's channel number is always identified above the waveform, to the left of the ECG key.



- ECG trace for first lead
- 2 telemetry channel number
- ECG key for first lead
- 4 QRS indicator (flashes once per detected beat)
- 6 ECG lead designator
- display resolution (monitor or extended)
- paced operation indication (pacemaker detection is enabled)
- 3 abnormals per minute alarm limit *
- ST segment level for first lead **
- abnormals in a row alarm limit *
- ECG rate alarm limits; split screen centrals display a bell symbol when alarms are enabled; bedsides display the rate alarm limits (120/40)
- 2 abnormals per minute counter *
- (B) current heart rate
- ECG lead designator for second lead
- ST segment level for second lead**
- **16** ECG key for second lead
- NIBP measurements: systolic/diastolic(mean) @ hours:minutes; SpO2 measurement (90343 only)
- Only appears with the MultiView I or II option in the adult mode with Arrhythmia detection enabled.
- ** Only appears in adult mode with the ST segment analysis option.

To monitor paced patients:

- 1 Touch ECG
- 2 Touch SETUP
- 3 Select PACED YES

Monitoring Paced ECG Patients

When monitoring pacemaker patients, use the paced feature to automatically enhance pacemaker spikes for display and eliminate them from the heart rate counter. The last setting you select is retained as the default.

If the interval between the pacemaker pulse and the QRS complex is greater than 150 milliseconds, the beat is considered to have originated in the atria and is not classified as a paced beat.

To prevent pacemaker pulses from being counted as actual beats, specialized circuitry removes the pacemaker pulses from the ECG signal and replaces them with pacemaker flags.



The optimal leads for monitoring paced patients may vary. In telemetry monitoring, pacemaker spikes are detected on lead II. If pacemaker spikes are not detected, change electrode position.



- ECG detection circultry may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon ECG rate alarms. Keep pacemaker patients under close surveillance.
- The system may insert pacemaker flags into the ECG signal in response to signals that are not pacemaker pulses. Therefore, if you use a Spacelabs Medical monitor to observe pacemaker performance, you must take into account all possible sources of pacemaker flags.
- Use the pacemaker manufacturer's performance analyzer as the primary means of evaluating pacemaker operation.

Restoring Default Settings

With the Module Configuration Manager feature, you can restore all default settings. User-configurable options are listed in the *Module Configuration Manager* chapter of this manual.



RESTORE SETTINGS changes the user-configurable options for all parameters in the module.

To restore default settings:

- 1 Touch ECG
- 2 Touch SETUP
- 3 Touch RESTORE SETTINGS
- 4 Select YES

To change the display resolution:

- 1 Touch ECG
- 2 Touch SETUP
- 3 Select MONITOR or EXTENDED

Changing the Display Resolution

The MONITOR/EXTENDED key determines the display resolution of the two ECG traces, whether or not both traces are currently displayed on the monitor.

Key	Display Resolution
Monitor	(0.5 - 30 Hz)
Extended	(0.05 - 30 Hz)



Changing the display resolution does not change the waveform bandwidth used to analyze the ECG signals for arrhythmia and ST segment level.

The factory default setting for display resolution is monitor mode.

To select ECG leads:

- 1 Touch ECG
- 2 Touch LEAD SELECT
- 3 Touch 1ST or 2ND LEAD
- 4 Select the desired lead

Selecting Options for Lead Display

One operational mode is available with the 90343 and 90347 multi-lead transmitters. When all electrodes are connected to the patient, leads I, II, III, AVR, AVL, AVF, and Vx, where x = 1 to 6, are available. When no chest lead is applied, leads I, II, III, AVR, AVL, and AVF are available using the remaining connected electrodes.

To discharge a patient:

- Disconnect the transmitter from the patient
- 2 Remove battery
- 3 Select YES to confirm signal loss permanent
- 4 Select YES to discharge
- 5 Select YES to purge data

Co	Connected Electrodes (X)				90343/90347
RL	С	LL	LA	RA	- Valid Lead Vectors
X	Х	Х	Х	Х	V1-6, I, II, III, AVR, AVL, AVF
Х	Х		X	Х	1
Х	Х	Х		Х	II
Х	Х	X	Х		III
Х		Х	Х	Х	I, II, III, AVR, AVL, AVF
X			Х	X	1
Х		Х		Х	II
Х		X	·X		111
	Х	Х	Х	Х	I, II, III, AVR, AVL, AVF
	Х		Х	X	1
	Х	Х		Х	II
	Х	Х	Х		III
\neg		Х	Х	Х	11



All combinations of leads not shown above result in no valid lead vectors. In general, for at least one valid vector, either RL or C and two limb leads must be connected.

ECG Troubleshooting

Refer to the ECG Problem Solving section in the ECG chapter of this manual for additional conditions and solutions.

ASYSTOLE

An ASYSTOLE message means it has been 5 seconds or more since a QRS complex has been detected. Check the patient. If the patient is all right, try the following:

- Check that the lead wires are inserted into the proper receptacle.
- Using the continuity tester, check that there is no damage to the lead wires.
- If the amplitude is poor, check the appropriate lead with a 12-lead ECG.
- Check that the transmitter is not too near (within 3 feet) a television receiver or other CRT displays.

ECG VOLTAGE TOO LOW

The ECG amplitude may have dropped below the R-wave detector threshold level. Reposition the electrodes to obtain a QRS amplitude of at least 0.20 mV (adult) and 0.15 mV (neonate).

NOISY SIGNAL

The patient may be moving excessively. Secure the lead wires to the patient.

- Check the electrodes for good skin adhesion.
- Check lead wires at the transmitter for good contact.

ECG Troubleshooting Guide

Clinical Situation	Possible Cause	Solution
Noisy signal	■ ECG frequency response set to extended mode	Select monitor mode
	■ Electrodes dry or poor skin adhesion	Repeat skin preparation and apply new, moist electrodes
Baseline wanders	Patient moving excessively	Secure lead wires by stress-looping to the patient
	Respiration artifact	■ Re-position electrodes
	Electrodes dry or poor skin adhesion	Repeat skin preparation and apply new, moist electrodes
Low amplitude ECG	Skin improperly prepared	Abrade skin and reapply electrodes
11	Lead selected not providing QRS complex with greatest amplitude	Select another lead for monitoring
	■ Electrodes could be positioned over bone or muscle mass	Re-position electrodes
ECG won't learn	ECG signal too noisy	Check lead wires and electrodes, then relearn patient rhythm
	ECG voltage not within threshold. ECG VOLTAGE TOO LOW message may be displayed	Select a different lead or adjust electrode location
Excessive alarms	Electrodes dry or poor skin adhesion	Repeat skin preparation and apply new, moist electrodes
	Alarm limits set too close to patient's normal heart rate	Readjust alarm limit
	Excessive patient movement or muscle tremor	Reposition electrodes and secure electrodes with tape if necessary

Refer to the *Problem Solving* sections in this chapter and in the *ECG* chapter for further monitoring tips.

SpO₂ Overview (90343 only)

Pulse oximetry enables you to noninvasively monitor a patient's hemoglobin oxygen saturation. This may be accomplished in either a continuous or episodic manner. The oximetry sensor contains two light emitting diodes (LEDs) that transmit specific wavelengths (660 and 940 nanometers) of light which are received by a photodetector.

Oxygen saturated blood absorbs light differently as compared to unsaturated blood. Thus the amount of light absorbed by the blood can be used to calculate the ratio of oxygenated hemoglobin to total hemoglobin in arterial blood. The monitor displays this ratio as percent SpO₂. Normal values range from 95 to 100%.



- A pulse oximeter should NOT be used as an apnea monitor.
- A pulse oximeter should be considered an early warning device. If a trend towards patient deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's condition.



If your module is equipped with the Module Configuration Manager feature, you can define your own default settings for such characteristics as alarm limits and display configuration. See the Module Configuration Manager chapter in this manual for further details.

Setting Up SpO₂ Monitoring

during defibrillation.

The model 90343 digital telemetry multi-parameter transmitter uses Spacelabs Medical sensors as well as those from other manufacturers. Refer to the *Sensors* section at the end of this chapter for information concerning specific sensors and their operation.



- Use only patient sensors specified by Spacelabs Medical.
 If you use sensors other than those specified, it may degrade performance and could damage the transmitter
- Check the sensor site frequently. Do not allow the sensor to remain on one site for a prolonged time period, especially when monitoring neonates. Refer to sensor manufacturer's instructions.
- Never attach an SpO₂ sensor on a limb being monitored with a blood pressure cuff or a limb with restricted blood flow.
- A poorly applied sensor may give incorrect saturation values.
- Choose a site with sufficient perfusion to ensure accurate oximetry values.

To set up SpO₂ monitoring:

Connect the adapter cable to the transmitter

- 2 Attach the sensor to the patient and connect the sensor cable to the adapter cable
- 3 Initiate ECG monitoring
- 4 Select ECG
- 5 Select CHANNEL FORMAT
- 6 Set SpO2 ON

PCMS

All sensors require an adapter cable between the sensor and the transmitter. Do not discard the adapter cable when you have finished using a disposable oximetry sensor. Disconnect the sensor cable from the adapter cable before discarding the sensor.

To connect the adapter cable to the transmitter, align the cable with the notch on the front of the transmitter connector and push the cable straight down into the transmitter. When you remove the cable, press the latch release (use a blunt device) on the bottom of the cable and pull the cable straight out. Never *twist* the cable.

Figure Telemetry-2: SpO₂ Adapter Cable to Transmitter

To enable SpO2 monitoring in the model 90343 digital telemetry multi-parameter transmitter, enable the SpO2 setting for DIP switch 5 beneath the battery compartment. (The factory default of this switch is ON.)

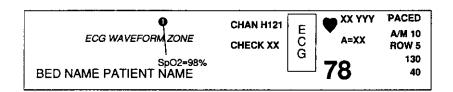


Figure Telemetry-3: Display Zone — Full Screen

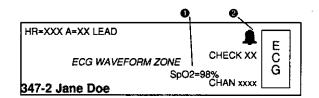


Figure Telemetry-4: Display Zone — Split Screen

- Current SpO₂ value (percent)
- The bell indicates that alarms are enabled (on split screen central only)

Ensuring Accurate Monitoring

While each sensor requires site specific application procedures, the following general points will aid in ensuring oximetry monitoring success.

- Choose a site that provides proper alignment of the LEDs and receiving photodetector.
- Reduce light interference when monitoring a neonate under bright light by using a diaper or other light block over the sensor.
- Select a site that has unrestricted blood flow and can remain as immobile as
 possible to reduce or eliminate movement artifact.
- Do not restrict blood flow when securing a sensor with tape.
- Do not select a site near potential electrical interference (electrical cords, for example).

Setting or Adjusting Alarm Limits

Pulse oximetry alarm limits and delays are based either on factory default limits or user-defined limits. The factory default settings for alarm limits are 100% for high and 85% for low. For alarm delays, the factory default settings are 15 seconds for alarm limit delay and 20 seconds for message alarm delay. Read the *Alarms* chapter in this manual for details concerning PCMS alarm operation.

Refer to the *Module Configuration Manager* chapter in this manual for SpO₂ parameter tables that list available user settings and factory defaults for this parameter.

ALM DELAY Key

This key sets the number of seconds delay the system will wait before it reports that an alarm limit has been violated. When this feature is off, the key label will read "ALM DELAY OFF". When it is on, the label will read "ALM DELAY xx" where "xx" is the value, in seconds, of the delay.

The caregiver can set the delay time by taking the following steps:

- Touch ALM DELAY xx (or ALM DELAY OFF).
- 2. Touch the up and down arrow keys until the value is set as desired. Possible settings are OFF, 5, 10, 15, 20, 25, and 30 seconds.



If the caregiver presses the down arrow key after the lowest value has been reached, the following message will appear on the prompt line:

Minimum alarm delay time has been reached.

 If the caregiver presses the up arrow key after the highest value has been reached, the following message will appear on the prompt line:

Maximum alarm delay time has been reached.

MSG ALM DELAY Key

This key sets the number of seconds delay the system will wait before it issues an alarm tone following any of the following messages:

- SpO2 MONITOR FAILURE
- SpO2 FAULTY SENSOR

To set or adjust alarms:

- 1 Touch ECG
- 2 Touch ALARM LIMITS
- 3 Select SpO2 ALARMS ON
- 4 Select Hi=, LO=, ALM DELAY, and MSG ALARM DELAY
- 5 Use arrow keys to adjust

- SpO2 SENSOR OFF PATIENT
- SpO2 INSUFFICIENT SIGNAL
- AMBIENT LIGHT INTERFERENCE
- SpO2 INSUFFICIENT SIGNAL
- SpO2 NOISY SIGNAL

When this feature is off, the key label will read "MSG ALM DELAY OFF". When it is on, the label will read "MSG ALM DELAY xx" where "xx" is the value, in seconds, of the delay.

The caregiver can set the message delay time by taking the following steps:

- 1. Touch MSG ALM DELAY xx (or MSG ALM DELAY OFF).
- Touch the up and down arrow keys until the value is set as desired. Possible settings are OFF, 10, 20, 30, 40, 50, and 60 seconds.



If the caregiver presses the down arrow key after the lowest value has been reached, the following message will appear on the prompt line:

Minimum message alarm delay time has been reached.

 If the caregiver presses the up arrow key after the highest value has been reached, the following message will appear on the prompt line:

Maximum message alarm delay time has been reached.

Setting SpO₂ Data Averaging Period and Sampling Interval

The SpO_2 data averaging selection is used to smooth the oximetry saturation value for averaging the patient input values over 4, 8, or 16 seconds. This selection is made by setting the DIP switches 1 and 2 beneath the battery compartment in the Model 90343 digital telemetry multi-parameter transmitter. The default value is 8 seconds. Refer to Figure Telemetry-5: DIP Switch Setting in Battery Compartment.

DIP Switch 1 DIP Switch 2		Effect
OFF	OFF	4 seconds averaging enabled
OFF	ON	8 seconds averaging enabled (default)
ON	OFF	16 seconds averaging enabled

Figure Telemetry-5: DIP Switch Setting in Battery Compartment

The sampling interval selection permits the caregiver to determine how often an SpO_2 measurement will be taken. Less frequent SpO_2 readings can extend the usable life of the the battery. (Refer to the Ultraview Digital Telemetry Products Data Sheet — P/N 061-0801-xx — for more information on battery service life.) This selection is made by setting DIP switches 3 and 4 beneath the battery compartment in the model 90343 digital telemetry multi-parameter transmitter. The default setting is 1 minute intervals.

DIP Switch 3	DIP Switch 4	Effect
OFF	OFF	Continuous sampling
OFF	ON	1 minute sampling interval (default)
ON	OFF	2 minute sampling interval
ON	ON	5 minute sampling interval

To display heart rate from SpO₂ sensor:

- 1 Touch ECG
- 2 Touch CHANNEL FORMAT
- 3 Read heart rate in the area to the left of the SpO2 ON/OFF key

Viewing Pulse Rate

In normal operations the heart rate for display will be obtained directly from the acquired ECG leads or an alternate rate source. SpO2 can be used as the alternate source, if it is set for continuous measurement. When it is set for episodic measurement, SpO_2 cannot be used as an alternate rate source.

SpO₂ Error Messages

Error messages indicate a problem or condition which may affect accurate monitoring values. Do not ignore these messages. Correct any fault before continuing.

When the following messages are displayed, the saturation value is immediately changed to ??? and an alarm is triggered, if your module has been configured with an alarm for that message. (Refer to the *Module Configuration Manager* chapter).

SpO2 SENSOR DISCONNECTED

- The transmitter does not detect an adaptor cable connected or a sensor connected to an adaptor cable. If the message persists and the adaptor cable is secure, replace the adapter cable.
- The alarm will stop after approximately 10 seconds.
- On remote view, there may be no audible alarm on the remote mainframe before the local alarm stops.

SpO2 MONITOR FAILURE

 The LED and/or photodiode have failed. Replace the sensor and/or SpO2 adapter cable.

When the following messages appear, the monitor displays the saturation value alternately with the message ??? every two seconds. An alarm will begin after the message alarm delay time has elapsed (Refer to the Module Configuration Manager chapter.)

SpO2 AMBIENT LIGHT INTERFERENCE

- The sensor is receiving external light interference from a bright light source near the sensor. Shield the sensor from the external light source. If the condition persists for more than 30 seconds, ??? will replace the data display.
- The sensor photodiode and LEDs are misaligned on flexible sensors thereby allowing light to enter. Realign the sensor photodiode with LEDs.
- If a message appears with finger clip, replace sensor.

SpO2 INSUFFICIENT SIGNAL

- Insufficient signal for proper operation.
- Poor sensor application or site. Correctly re-apply or reposition to a better perfused site, massage site, or apply new sensor.

SpO2 NOISY SIGNAL

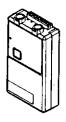
- The sensor signal is disturbed by motion or other interference. Eliminate sensor movement. The message disappears when a value is obtained.
- The sensor is placed adjacent to power cords or other electrically noisy devices. Movethe noisy device or move the sensor to another site.

SpO2 SENSOR OFF PATIENT

- The transmitter is unable to detect a valid sensor input signal. Check the patient for proper sensor placement.
- Tissue between the LED and photodiode is too transmissive. If sensor placement seems correct and the message persists, try a sensor site with a thicker tissue bed.



Adaptor cables and sensors are ordered separately through the Spacelabs Medical Supplies Products..



Nellcor adaptor cable (P/N 012-0587-00)

Nellcor sensor

90343 digital telemetry multi-parameter transmitter

Figure Telemetry-6: Nellcor and Sensors and Adaptor Cables

SpO₂ Troubleshooting Guide

Clinical Situation	Possible Cause	Solution
No SpO ₂ label is displayed	■ SpO ₂ is not enabled at the 90343	■ Be sure transmitter DIP switch 5 setting is ON ■ Be sure DIP switch 8 is OFF
SpO ₂ value displays ???	Sensor not connected to patient	Reattach sensor
	Adapter cable not connected to module properly	Correctly connect the adapter cable
	Sensor not connected to adapter cable	Correctly connect the sensor
·	Excessive patient motion	Urge patient to remain still while reading is in progress
	■ Transmitter is in the initialization phase (the first 15 seconds after sensor application)	Wait until initialization is complete
Low signal strength	Sensor placement not optimum	■ Move sensor to a site which has better perfusion
		Align LED with sensor photodetector
	Sensor placed below blood pressure cuff	■ Move sensor to an alternate limb
Intermittent or complete failure to operate	■ Transmitter error	Call qualified service person
	■ Depleted battery	Replace battery
Factors which cause significant variances in sensor accuracy	Presence of dysfunctional hemoglobins (COHb, MetHb)	Follow hospital procedure for determining oxygenation in these patients
	Presence of intravascular dyes (indocyamine green, methylene blue) depending on their concentration in the blood stream	Follow hospital procedure for determining oxygenation in these patients
	High ambient light level	■ Reduce light levels near patient
	■ Electrosurgical interference	Follow hospital procedure for determining oxygenation in these patients during the procedure
	■ Patient is significantly anemic (Hb less than 5gm/dl) or patient has received large amounts of IV solutions	Follow hospital procedure for determining oxygenation in these patients

NIBP Overview



90217 ABP Monitor

The model 90343 digital telemetry multi-parameter transmitter can send the non-invasive blood pressure (NIBP) patient data acquired by the Model 90217 ambulatory blood pressure (ABP) monitor, to the Model 90478 digital telemetry receiver. The Model 90478 can display the patient's episodic NIBP data and trigger alarms based on thresholds set at the Central Station monitor by the clinician.

The Model 90217 ABP monitor is a small, lightweight, battery-powered unit designed to take blood pressure and heart rate measurements for 24 or 48 hours or for longer periods of time. Please refer to the *90217 Operations Manual* (070-0137-xx) for more detailed information on this specific product; its initialization via a Local Report Generator (Model 90239A) or direct PC interface (Model 90121); Patient Preperation; Data Transfer and Reports; and Event Codes.

Noninvasive blood pressure (NIBP) uses oscillometric monitoring to measure systolic (S), diastolic (D), and mean (M) arterial blood pressures. The PCMS monitor displays these readings and the time the measurement was acquired. You can also display heart rate. The ABP monitor can display up to ten readings at one time and store up to 120 readings.



The Model 90217 ABP Monitor is intended for use with adult patients only.

Setting Up NIBP Monitoring

Proper cuff selection and application is a critical issue in ensuring the accuracy of NIBP readings. To ensure proper cuff selection, first measure the circumference of the limb at its midpoint. Match the limb measurement to the range of appropriate circumferences (in centimeters) specified on each cuff. If the cuff bladder is too wide for the patient, the reading will be falsely lowered; if too narrow, the reading will be falsely elevated. Undersizing the cuff results in the greatest chance of error, so a variety of cuff sizes should be available to accommodate your full patient population.

The cuff should be snugly applied. When the cuff is properly applied to an adult, you should be able to insert one finger between the cuff and the arm. If you can insert two fingers, the cuff is too loose which may result in falsely elevated readings. Make sure the hose is not kinked when the cuff is applied.

During blood pressure measurement, the inflated cuff reduces blood flow to the limb to which it is applied. Do not apply a cuff to a limb that has restricted blood flow. Check the patient periodically.



- Do not apply a blood pressure cuff to a limb being monitored with a pulse oximetry sensor because SpO₂ will be affected during NIBP readings. Avoid applying a cuff to a limb that has an intravenous line in place. Do not apply a cuff to a limb that has restricted blood flow.
- Never use extensions or adapters with the neonatal hose. Use only single hose cuffs to ensure proper operation. Spacelabs Medical's hoses are non-conductive with respect to defibrillator discharge effects.

To set up NIBP monitoring:

- Attach appropriate cuff and 90217 ABP monitor to patient
- 2 Attach adapter cable between 90217 and 90343
- 3 Initialize 90217 with 90239A local report generator
- 4 Configure 90343 DIP switch 6 to enable NIBP operations
- 5 Initiate ECG monitoring
- 6 Select ECG
- 7 Select CHANNEL FORMAT
- B Set NIBP ON

Patient Factors Affecting Readings

Excess patient movement, speech, or muscle contractions as a result of severe pain or shivering can interfere with automated NIBP readings. Ensure that the patient is quiet and not moving during NIBP readings just as you would manual readings. Avoid applying external pressure to the cuff during readings. Institute measures to minimize shivering and alleviate pain.

Some arrhythmias may cause beat-to-beat pressure fluctuations that can make obtaining NIBP readings more difficult. Increased variability of readings can result from these pressure variations. If it becomes difficult to obtain readings in the presence of arrhythmia, pressure should be temporarily verified using another method. Pressure also varies cyclically with normal respiration. With deep respirations or in certain patients this effect may be enhanced, increasing reading variability.

For patients in shock, indirect methods of measuring pressure (auscultatory, oscillometric, Doppler) may not be reliable because of peripheral vascular changes. These changes include peripheral vasoconstriction and diminished peripheral circulation resulting from shunting of blood to central organs. In some cases peripheral pulses or Korotkoff sounds may be diminished or disappear in spite of adequate blood pressure. In such cases, measuring a cuff pressure may be impossible or give misleading results. Direct blood pressure measurements (invasive) should be considered in patients with signs of shock or any patient who rapidly becomes unstable for unknown reasons.

Setting Up the ABP Monitor

After the monitor has been initialized, prepare the patient for monitoring as follows:

- Turn on the monitor (wait for the monitor to perform self-tests). When the LCD displays the current time, the monitor is ready for operation.
- Strap the monitor to the patient on the hip opposite the side on which the cuff
 is worn. Secure the monitor using the patient's own belt or the ABP pouch
 strapped over the opposite shoulder. When using the shoulder strap, use the
 belt supplied with the monitor or the patient's belt to provide additional
 security.
- To select the proper cuff, first measure the circumference of the limb at the
 point where the cuff is to be applied. Match the limb measurement to the range
 of appropriate circumferences (in centimeters) specified on each cuff (refer to
 the table below).

Cuff Size	Limb Circumference
Pediatric	13 to 20 cm
Small Adult	17 to 26 cm
Average Adult	24 to 32 cm
Large Adult	32 to 42 cm
Extra-large Adult	38 to 50 cm

4. Position the cuff so that the center of the inflatable bladder is directly over the brachial artery. The center of the bladder location is marked on the outside of the cuff. Once the proper position is determined, the cuff must be tightened to

ensure that it is equally snug at the top and bottom edges and that it is not kinked. This is especially important on larger arms. Insert a finger between the cuff and the limb to ensure it is not too tight. It may be necessary to wrap the cuff with its tail at an angle to achieve uniform tightness. If the cuff is not equally snug at the top and bottom edges, the number of readings available will be limited and the monitor may indicate that the cuff is improperly applied.



- Use only Spacelabs Medical cuffs with this monitor. Using other manufacturer's cuffs may result in inaccurate readings even if the manufacturer's recommended size is observed.
- If the cuff is too small, pressure readings may be falsely high; a cuff that is too large produces a falsely low reading. The bladder can be positioned in the cuff for either the left or right arm.



- Avoid compression or restriction of pressure in the NIBP patient connector tubes. Check that operation of the equipment does not result in prolonged impairment of circulation.
- Do not apply cuff to areas of breached or injured skin.
- Cuff hose connections use luer fittings. Be careful not to connect the ABP monitor into an intravenous fluid line when working close to them.
- This product contains natural latex rubber components to which some people may be allergic. These components include the bladder and the first four inches of tubing extending from the cuff.
- Once cuff is applied, the arm should be relaxed at the patient's side. To avoid reading errors due to hydrostatic pressure differences, the level of the cuff on the arm should be near the level of the heart.
- 6. Lead the hose up the arm with the cuff and place it across the back of the patient. Drape the hose so it does not cause the patient discomfort and is not pinched shut by too tight a radius. Figure Telemetry-7: Common Cuff Hose Positions shows the most common positions for the cuff hose.

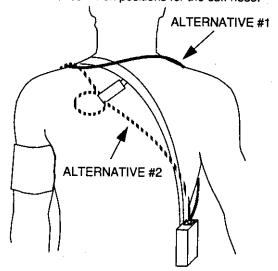


Figure Telemetry-7: Common Cuff Hose Positions

- 7. Connect the hose to the monitor.
- 8. To verify proper monitor operation, take one or more blood pressure readings. Push the START/STOP key to begin a measurement.
- 9. Interconnect the adapter cable between the communications port on the 90217 and the NIBP port on the 90343 as shown in *Figure Telemetry-8: Transmitter and ABP Monitor Connections.*

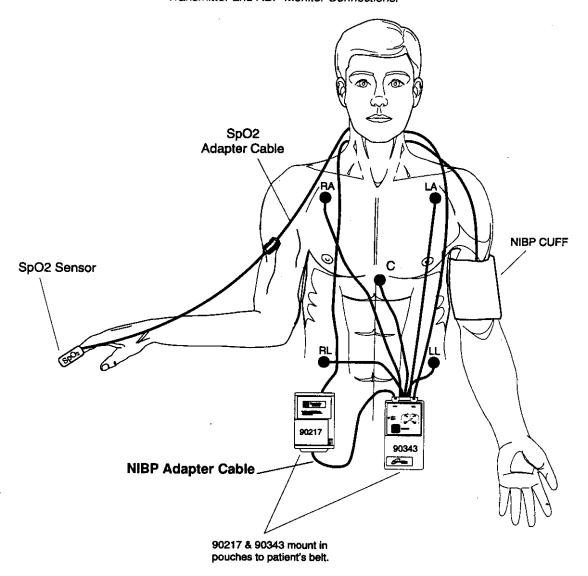


Figure Telemetry-8: Transmitter and ABP Monitor Connections

Figure Telemetry-9: Display Zone — Full Screen and Figure Telemetry-10: Display Zone — Split Screen illustrate typical NIBP displays. You can view NIBP readings from any PCMS bedside or central monitor on a network. NIBP displays on a split screen central monitor appear in a format slightly different from that of bedside or full screen central monitors.

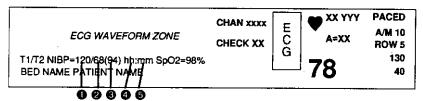


Figure Telemetry-9: Display Zone — Full Screen

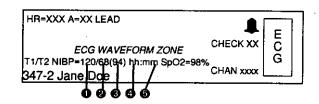


Figure Telemetry-10: Display Zone - Split Screen

- Last systolic reading
- Last diastolic reading
- Last mean reading
- Hour of day of last reading
- 6 Minutes after the hour of last reading

Setting or Adjusting Alarm Limits

You can define pressure alarm limits for systolic, diastolic and mean values. The default setting for alarms is OFF. Read the *Alarms* chapter in this manual for PCMS system alarm functions. The alarm limits defaults are listed in *Table 1:* Alarm Limits.

Table 1: Alarm Limits

	Ні		Low	
systolic	150 mmHg	(20.0 kPa)	100 mmHg	(13.5 kPa)
diastolic	100 mmHg	(13.5 kPa)	60 mmHg	(8.0 kPa)
mean	110 mmHg	(14.5 kPa)	90 mmHg	(12.0 kPa)

Refer to the *Module Configuration Manager* chapter in this manual for NIBP parameter tables that list available user settings and factory defaults for this parameter.

To set or adjust alarms:

- 1 Touch ECG
- 2 Touch ALARM LIMITS
- 3 Select NIBP/ALM ON
- 4 Select SYS, DIA, or MEAN

Control of the second of the s

- 5 Select HI= or LO=
- 6 Use arrow keys to adjust

PCMS

To display heart rate from the ABP monitor:

- 1 Touch ECG
- 2 Touch CHANNEL FORMAT
- 3 Read heart rate in the area to the left of the NIBP ON/OFF key

Displaying Heart Rate Data

in normal operation, the heart rate for display will be obtained directly from the acquired ECG leads or an alternate source (SpO₂). The ABP heart rate is not available as an alternate heart rate source due to the episodic nature of the NIBP measurement.

Displaying New or Previous Readings

90217 Event Codes

The ambulatory blood pressure monitor will display an event code whenever an event prevents the unit from successfully completing a blood pressure measurement. The two numerical digits of the event code indicate the reason the measurement was aborted. The table below lists event codes that are displayed on the monitor, as well as event codes that appear on the Event Code Report.

Monitor	Report	Condition
EC00		
	EC10	Excess movement artifact. Frequent EC10 messages may indicate an air leak.
	EC20	A) A very large number of movement artifacts B) Heart rate arrhythmia
	EC30	A) Movement artifact at mean arterial pressure B) Heart rate arrhythmia
	EC40	A) Movement artifact at asystole B) Heart rate arrhythmia
	EC50	A) Movement artifact at diastole B) Heart rate arrhythmia
	EC60	A) Movement artifact B) Heart rate arrhythmia
	EC70	Systole was found to be above the highest cuff pressure. However, this result appears to be an error caused by motion artifact. Therefore, the cuff will not be inflated to a higher pressure on the next measurement attempt.
	EC80	A) Movement artifact B) Heart rate arrhythmia
-	EC90	A) Movement artifact B) Heart rate arrhythmia
EC01		
	EC11	Did not pump above the mean arterial level
	EC21	Did not pump above systolic pressure
	EC91	Systole appears higher than the selected maximum cuff pressure limit
EC02		
	EC12	Did not reach initial cuff pressure. The cuff may have been improperly applied or there may be an air leak.
	EC22	Overpressure
	EC32	Overpressure
	EC42	No cuff attached
	EC52	Kinked hose
	EC62	Cuff applied too loosely
	EC72	Kinked hose

PCMS

Monitor	Report	Condition
	EC82	Kinked hose.
EC03		·
	EC03	Patient canceled reading by pressing STOP key. No retry attempt is made following an EC03 code.
	EC13	The Office Check Mode has been reinstated. No retry attempt is made following an EC13 code.
EC04		
	EC04	Blood pressure measurement not completed in the maximum time allowed. Occasional EC04 messages may result from excessive patient movement. Frequent EC04 messages would indicate an improperly applied cuff or a monitor malfunction which requires service.
	ECn4	(where n = 1 to 9) Indicates that one or more of the blood pressure results have been corrupted and subsequently recovered. Frequent occurrence of this message would indicate a malfunction which requires service.
	EC05	The individual blood pressure result has been corrupted and cannot be recovered.
EC15		Equipment malfunction. Return to Spacelabs Medical for service.
EC25		Unit failed to initialize. Please initialize.
EC35		The monitor needs to be reinitialized.
EC05		
EC05 & EC45	EC45	Invalid bleed size. The monitor automatically has changed the bleed size to 8 mmHg.
EC05 & EC55	EC55	An unexpected loss of power possibly caused by a) removal of the batteries during a blood pressure measurement, b) hardware overpressure, or c) a hardware time-out. Frequent EC55 messages would indicate a malfunction which requires service.
EC05 & EC65	EC65	Extremely large artifact.
EC05 & EC75	EC75	Equipment malfunction. Return to Spacelabs Medical for service.
EC05 & EC85	EC85	Equipment malfunction. Return to Spacelabs Medical for service.
EC05 & EC95	EC95	Cuff pressure baseline out of bounds. The monitor should correct the baseline automatically within 10 minutes; or it can be set by initialization of the monitor. If initialization does not correct the condition the monitor must be returned to Spacelabs Medical for calibration.
EC07	:	
	EC78	Clogged luer filter
EC08		
	EC18	Too few data entries to accurately determine blood pressure. The message may indicate that the cuff is not being worn by the patient (taken off but left connected to the monitor). The message may also indicate that motion artifacts cause the majority of the incomplete data.
	EC28	Diastole above 200 mmHg

Monitor	Report	Condition	
	EC38	Pulse pressure less than 16 mmHg	
	EC48	A) Movement artifact at mean arterial pressure B) Heart rate arrhythmia	
-	EC58	A) Movement artifact at diastole B) Heart rate arrhythmia	
	EC68	Division by zero	
EC09			
	EC19	Contradictory instructions sent to hardware (e.g., "pump on and valve open")	
	EC29	Diastolic pressure value cannot be obtained from the data available.	
.	EC39	Algorithm could not process input data quickly enough resulting in an input queue overflow.	
	EC49	This monitor must be initialized.	
	EC59	Heart rate value cannot be obtained from the data available.	
	EC69	Heart rate value cannot be obtained from the data available.	
	EC79	Bleed steps were too small. This may be caused by a partially obstructed air hose. All blood pressure attempts following this message are inhibited. Attempts can be enabled by turning the power switch off then on.	
	EC99	Unexpected or contradictory data (such as a negative cuff pressure).	
LLL			
	EC16	Low battery detected prior to start of measurement.	
	EC26	Low battery detected after measurement started. Usually caused by the pump drawing enough current to lower the battery voltage.	
Lbb		The report does not print an event code for this condition, which is a low backup battery. Contact Spacelabs Medical for replacement of the battery.	

NIBP Troubleshooting Guide

}	Clinical Situation	Possible Cause	Solution
,	No NIBP displays	Adapter cable not inserted correctly NIBP not enabled on 90343 or 90478 ABP monitor not properly initialized	Remove and re-insert adapter cable Enable NIBP function by setting transmitter DIP switch 6 ON and setting DIP switch 8 OFF Reinitialize ABP Monitor
	No NIBP readings can be obtained	Incorrect or inoperative cuff in use	Replace with cuff known to be operative
		Cuff tubing is attached to adult outlet, but monitor is configured in the neonatal mode (or vice versa)	Connect tubing to correct outlet. Correlate monitor mode, cuff and patient type.
		Tubing is kinked	Locate kink and straighten tubing
		Some arrhythmias (e.g. atrial fibrillation and frequent ventricular ectopy) may cause a single or repeated failure to obtain a reading (may be due to true beat-to-beat variations in pressure)	Document arrhythmia if present, verify pressure with another method, then follow hospital procedure for care of this type of patient
	·	Excessive patient motion or muscle contractions associated with shivering or severe pain	Ensure that patient is quiet with minimal movement during NIBP readings. Minimize patient's shivering.
		■ Blood pressure outside of measurement range	■ Verify extremely high or low pressure with another method
	Intermittent or complete failure to operate	ABP monitor error	Remove ABP monitor from service; record event code; and call qualified service person
	Apparent incorrect value	■Wrong size cuff for patient	Measure patient's limbs at the midpoint. Match limb measurement to range specified on cuff (undersizing the cuff results in the greatest degree of error).
		Cuff is damaged	Replace with good cuff
		Excessive patient motion, shivering or severe pain	Ensure patient is quiet with minimal movement during NIBP readings. Minimize patient's shivering.
	·	False high readings may be the result of venous congestion caused by frequent readings	Reduce frequency of readings
		■Cuff too loose or positioned incorrectly	■Tighten cuff or reposition appropriately
	Variable readings occur	Some arrhythmias may cause beat-to- beat pressure and NIBP readings	Document arrhythmia if present, verify pressure using another method, then follow hospital procedure for care of this type of patient
		Larger than normal influence of respiratory phases on blood pressure (inspiratory fall in blood pressure; expiratory rise)	■NIBP software usually compensates for normal variation
q	lo NIBP readings or uestionable values in the resence of shock	Peripheral vascular changes experienced during shock may reduce the reliability of blood pressure readings obtained with any indirect method. Peripheral pulses may be diminished or absent.	Consider invasive pressure measurements in patients with symptoms of shock or in any patient who rapidly becomes unstable for unknown reasons

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General Telemetry Overview

The digital telemetry receiver module (Model 90478) when used in conjunction with Spacelabs Medical telemetry transmitters, PCMS[™] or Ultraview monitor, and modular receiver housing (Model 90479), provides continuous monitoring of electrocardiographic signals in order to detect abnormal cardiac rhythms, including life-threatening arrhythmias such as asystole, ventricular fibrillation, and ventricular tachycardia. In addition, when used with the digital telemetry multi-parameter transmitter (model 90343), monitoring of electrocardiographic signals is augmented by the availability of continuous or episodic SpO₂ measurements and episodic NIBP measurements.

Transmitters

The transmitter is a small battery-powered device carried by the patient to monitor ECG activity and SpO₂/NIBP (90343 only) data, and transmit this information to the telemetry receiver module.

- The 90343 and 90347 transmit four leads of ECG and use up to five lead wires.
 However, only two leads may be displayed simultaneously.
- The 90343 is also capable of transmitting numerical NIBP and SpO₂ data. This
 data is displayed simultaneously with that of the ECG waveform data.

Each telemetry channel requires its own transmitter operating at a unique radio frequency. Channel receivers are tuned from the touchscreen on the monitor to receive the available transmitter frequencies.



Operation of this equipment may be subject to licensing requirements by your local telecommunications authority. Please check with your Spacelabs Medical customer service representative.