

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

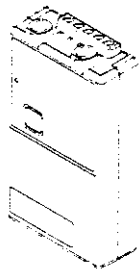
EXHIBIT 15 - Operators Manual Draft

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

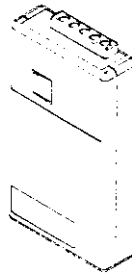
1. INTRODUCTION
 - 1.1 Overview
 - 1.2 System Components
 - 1.3 Transmitter
 - 1.4 Receiver Module
 - 1.5 Receiver Housing
2. SETUP
 - 2.1 Unpacking
 - 2.2 Receiver Configuration
 - 2.3 Transmitter Configuration
 - 2.4 Telemetry Biomed. Operations
 - 2.5 Biomed. Telemetry Functions
3. THEORY OF OPERATION
 - 3.1 Transmitter
 - 3.2 Receiver
 - 3.3 Housing
4. MAINTENANCE
 - 4.1 Care and Cleaning
 - 4.2 Physical Inspection
 - 4.3 Preventive Maintenance
 - 4.4 Safety Verification
 - 4.5 Disassembly/Assembly
 - 4.6 Transmitter Field Alignment Procedures
5. TROUBLESHOOTING GUIDE
6. REPLACEMENT PARTS LIST
7. SYMBOLS

DRAFT

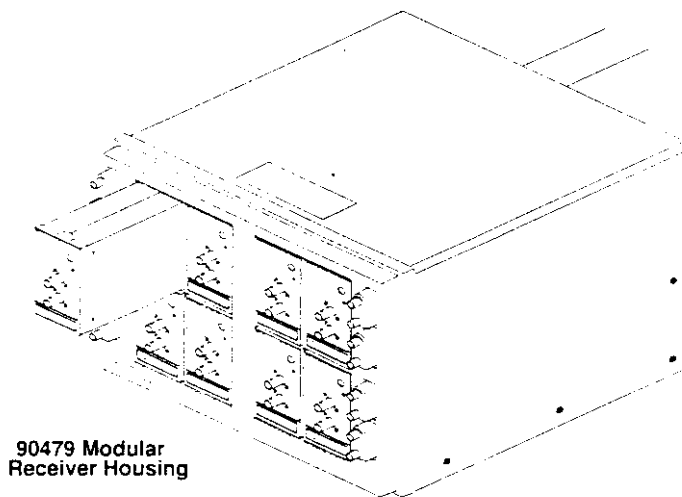


90343
Digital
Telemetry
Multi-parameter
Transmitter

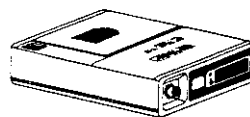
90347
Digital
Telemetry
ECG
Transmitter



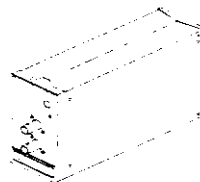
Diversity Antenna
System



90479 Modular
Receiver Housing



90217 ABP Monitor



90478 Modular Receiver

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, 90478

SPECIFICATIONS

TRANSMITTER PHYSICAL DIMENSIONS

90343 (Multi-Parameter)

Height: 5.25 in (13.3 cm)
Width: 2.85 in (7.2 cm)
Depth: 1.18 in (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 ($\pm 10\%$)

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 — $< 30\mu\text{V}$ p-p, rti, at 30Hz bandwidth

CMRR — $> 85\text{dB}$ (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 $< 500\text{mV}$

Resolution — $2.5\mu\text{V}$ per LSB, rti

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

Gain Accuracy — $\pm 5\%$

Pacer Rejection — Baseline shift < 0.2 mV (measured at ECG $\times 1,000$ 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 μsec

Signal Bandwidth — 0.05 to 30 Hz $\pm 10\%$ (-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

Connector: 3-conductor TT phone jack

Dynamic Range: $\pm 5\text{mV}$ ($\pm 10\%$), rti

Gain: ECG $\times 1000$ ($\pm 5\%$)

Bandwidth: 0.05 to 30 Hz $\pm 10\%$ (-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 abnormalities per minute; provides additional alarms for abnormalities per minute and abnormalities 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 abnormalities, tachycardia, pauses, ventricular and atrio-ventricular pacing; provides additional alarms for abnormalities in a row, abnormalities 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 bpm; alarms automatically enabled over a range of 40 (adult) or 100 (neonatal) to 300 bpm

Accuracy — $\pm 1\%$ 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 continuously 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 — 1 mmHg

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

Height: 4.46 in (11.32 cm)

Width: 2.24 in (5.68 cm)

Depth: 7.00 in (17.78 cm)

Weight: 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: 13.5 in (34.3 cm)

Depth: 17.5 in (44.5 cm)

(includes protective cover)

Weight: 32.0 lbs (14.6 kg)

(without modules loaded)

POWER REQUIREMENTS

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

ENVIRONMENTAL REQUIREMENTS

Operating —

Temperature: 50° to 104° F (10° to 40° C)

Humidity: 10% to 95% (non-condensing)

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

Storage —

Temperature: -40° to 149° F (-40° to 75° C)

Humidity: 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

Belt Clip

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,
90478**

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

Ultraview Care Network, PCMS, and
Multiview are trademarks of Spacelabs
Medical, Inc.

Other brands and product names are
trademarks of their respective owners.

All specifications are subject to change
without notice.

© Spacelabs Medical, Inc. 1998

061-0801-00 Rev. A 08/98

SPECIFICATIONS

ABP Adapter Cable
Part Number: 012-588-00
ABP Pouch
Part Number: 015-501-00

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

SPACELABS MEDICAL SpO₂ SENSORS ACCURACY AND SENSOR SELECTIONS

Sensor Accuracy — Each sensor at $\pm$ one
standard deviation:
80-100% $\pm 2\%$ absolute saturation
60-79% $\pm 3\%$ 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%, $\pm 3\%$ absolute saturation

Nellcor Disposable SpO₂ Sensors —

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

Table 1: Transmitter Battery Service Life¹ (hours)

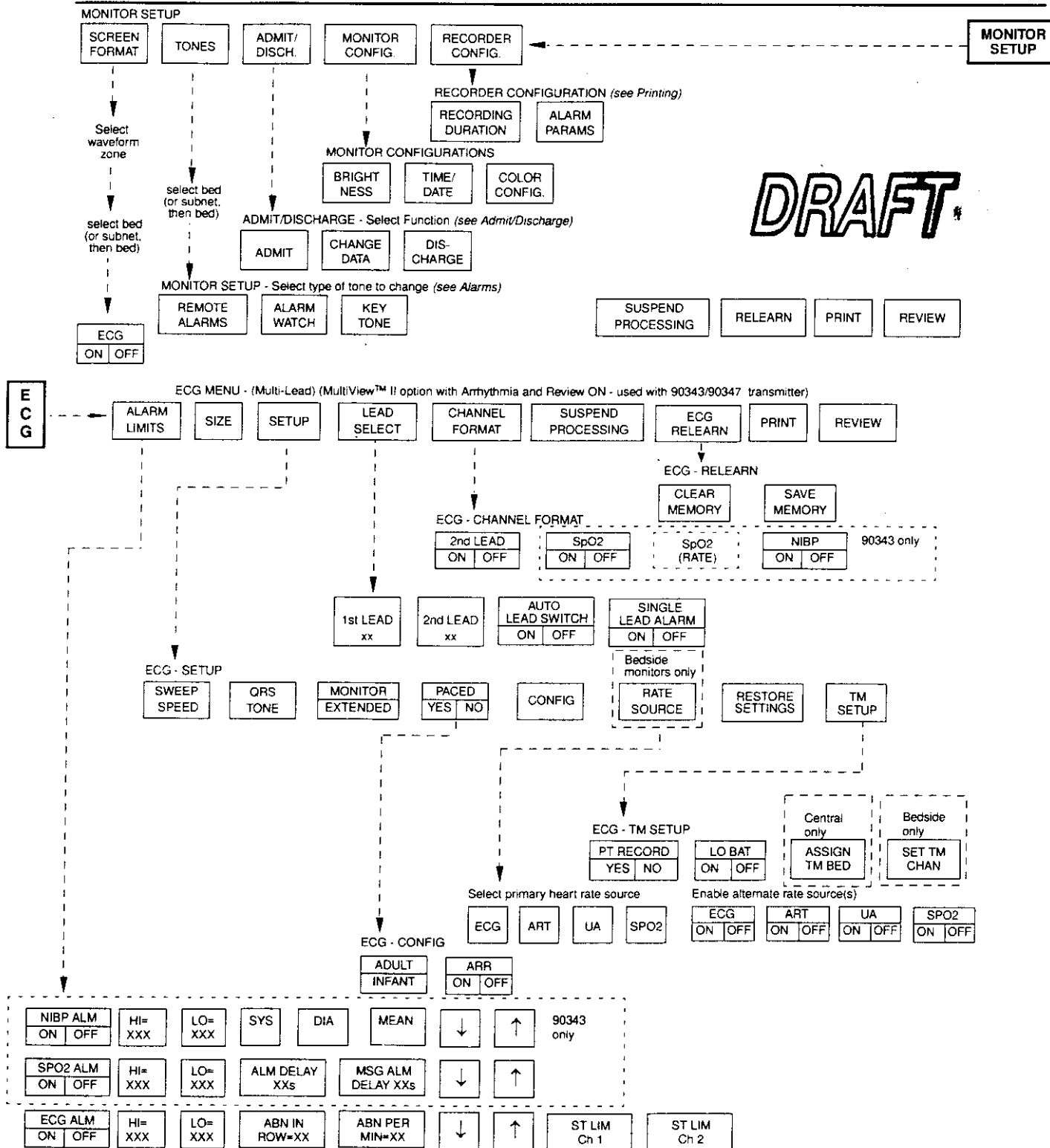
Battery Type	9 Volt Alkaline					9 Volt Lithium				
Load Conditions ²	ECG Only	ECG and Continuous SpO ₂	ECG and 1 minute Episodic SpO ₂	ECG and 2 minute Episodic SpO ₂	ECG and 5 minute Episodic SpO ₂ and NIBP	ECG Only	ECG and Continuous SpO ₂	ECG and 1 minute Episodic SpO ₂	ECG and 2 minute Episodic 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

¹ Operational service life in hours assuming a freshly charged battery used until the local "low battery" indicator begins to flash.

² 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.

ULTRAVIEW DIGITAL TELEMETRY

Directory



DRAFT



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

NOTE