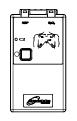
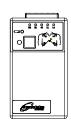
**Exhibit G: User Manual 1** 

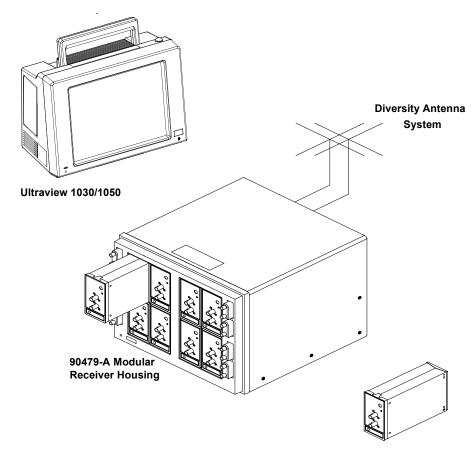
FCC ID: CM676A91341-600





91343 Digital Telemetry Multiparameter Transmitter 91341/47 Digital Telemetry ECG Transmitters









90217 ABP Monitor

# Ultraview<sup>®</sup> Digital Telemetry 91341, 91343, 91347, 90478, 90479-A

- Operation in the Wireless Medical Telemetry Service (WMTS) bands (608-614, 1395-1400, 1427-1429.5, 1429-1431.5 MHz).
- Approved to operate under FCC Part 95 rules.
- **■** ECG and multiparameter transmitter.
- ECG, SpO<sub>2</sub>, and NIBP (optional) for ambulatory patients.
- Touchscreen control of all module functions and compatible with all Ultraview Care Network<sup>™</sup> monitors.
- Lightweight, water resistant transmitters.
- Tunable transmitters.
- Diversity antenna system.
- Tunable modular receiver.
- Modular receiver converts bedside monitors to telemetry operation.
- Multi-lead ECG with ST segment analysis option; comprehensive arrhythmia and ST trending.
- Module Configuration Manager enables the hospital to customize the receiver's ECG patient monitoring functions to specific patient populations, clinical protocols, or operating preferences.
- Graded alarm functions enables the hospital to define high, medium, or low alarm tones according to critical, warning, or advisory event severity.
- Expanded central monitoring of ambulatory patients outside central antenna coverage.

# Ultraview Digital Telemetry 91341, 91343, 91347, 90478, 90479-A

# SPECIFICATIONS PARAMETER CHARACTERISTICS

#### **ECG**

Maximum Input — ±4 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-v, refered to input (rti), at 30 Hz bandwidth

**CMRR** — > 85 dB (monitor mode)

QRS Detection — Detects QRS complexes with durations of 40 to 120mS and amplitudes of 0.2 to 4.0 mV (adult) or 0.15 to 4.0 mV (neonatal)

**Defibrillator Protection** — Meets IEC 60601-2-27, AAMI EC-13

**Resolution** — 2.5 μV per LSB, rti

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

Gain Accuracy — ±5%

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

Pacer Detection — Detects pacer pulses of  $\pm 2$  mV to  $\pm 700$  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 ±10% (-3 dB)

Sample Rate — 120 samples per second SpO<sub>2</sub>

#### SpO<sub>2</sub> Sensor Interface —

Red LED drive (max): 175 mA peak at 10% duty cycle

IR LED drive (max): 105 mA peak at 10% duty cycle

SpO<sub>2</sub> Measurement Method — Functional saturation (oxygen saturation of functional hemoglobin).

SpO<sub>2</sub> Measurement Mode — Continuous, episodic (2 minutes, 5 minutes, and 30 minutes) sampling intervals; factory default setting is continuous.

#### ST Segment Analysis

Resolution — 0.08 mm

Range —  $\pm 9$  mm (1 mV = 10 mm)

Leads — ST Segment Analysis continously performed on up to seven leads. Alarms — Single lead or multiple leads; individual leads can be deselected. Alarms for absolute minimum and maximum ST levels; changes in ST level over the last 5 minutes.

**Displays** — ST values: minimum/maximum/ current ST segment deviation and 5 minute averaged segments for the last 30 minutes.

**Measurement Points** — Adjustable ST, PR, and J Points

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

# PATIENT MONITOR DISPLAY CHARACTERISTICS

#### **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; heart rates > 300 bpm are displayed as "+++".

**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

**Display Bandwidth** — Two settiings: 0.5 to 30 Hz  $\pm 10\%$  (-3 dB) in monitor mode, and 0.05 to 30 Hz  $\pm 25\%$  (-3 dB at 50 mm per second) in extended mode.

#### SpO<sub>2</sub> Display

**Measurement Range** — 30 to 100% O<sub>2</sub> Saturation

Saturation Accuracy — Sensor Dependent

Saturation Resolution — ±1%

Pulse Rate Range — 30 to 250 bpm

Pulse Rate Resolution — 1 bpm

**Alarms** — High and low saturation values; factory default limits are: high 100%; low 85%.

High range: 31% – 100% Low range: 30% – 99%

Numeric Update Rate — Every 2 seconds for continuous SpO<sub>2</sub> readings.

#### **SPECIFICATIONS**

### **NIBP Display**

(Refer to specifications for the 90217 ABP Monitor)

#### Measurement Range (adult only) —

Systolic: 8.0 – 35.0 kPa

(60 - 260 mmHg)

Diastolic: 9.0 – 27.0 kPa

(30 - 200 mmHg)

Mean: 5.3 – 31.0 kPa

(40 - 230 mmHg)

Pressure Accuracy — ±2% or ±3 mmHg

(whichever is greater)

Resolution — 1 mmHg

**Time Between Readings** — selectable, from 6 to 120 minutes

**Alarms** — High and low alarms for all measured parameters.

High range: 8.0 - 35.0 kPa

(60 - 260 mmHg)

Low range: 4.0 – 27.0 kPa

(30 - 200 mmHg)

#### TRANSMITTERS (91341, 91343, 90347)

**ECG Transmission** — View 2 of 7 available leads from two vectors (91341) or four vectors (91343, 91347) synchronized RF digital signal.

Electrode Configuration — Individually replaceable DIN standard safety lead wires. Local lead fault indicators for each lead wire.

Multiparameter Transmission (90343) — SpO<sub>2</sub> (saturation, SpO<sub>2</sub> sensor status, pulse rate) and optional NIBP (systolic, diastolic, mean pressure, measurement time, alarm conditions) with the model 90217 ABP monitor.

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

Output Power — 1 mW ERP, typical

Spectral Efficiency — 0.11 bps/Hz

**External Indicator** — Yellow LED flashes when battery level is low

**Battery** — 9 V battery; refer to *Table 1* for battery life expectancy

#### WMTS Frequency Band Option —

**-05**: 608-614 MHz **-09**: 1395-1400 MHz

1395-1400 MHz 1427-1429.5 MHz 1429-1431.5 MHz

## **Transmitter Physical Dimensions**

## 91343 (Multiparameter)

 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):

8.5 oz (241.0 gm)

#### 91341/47 (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):

6.78 oz (192.7 gm)

#### **MODULAR RECEIVER**

#### Module Includes:

Module Configuration Manager capability (refer to the Module Configuration Manager chapter of the Ultraview Care Network Operations Manual [P/N 070-1001-16] for complete feature specifications).

**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:  $\pm 5$  mV ( $\pm 10\%$ ), rti Gain: ECG x 1000 ( $\pm 5\%$ ) Bandwidth: 0.05 to 30 Hz  $\pm 10\%$  (-3 dB)

**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.

Receiver Sensitivity — Usable ECG signal to -95 dBm Ultraview Digital Telemetry 91341, 91343, 91347, 90478, 90479-A

# Ultraview Digital Telemetry 91341, 91343, 91347, 90478, 90479-A

#### **SPECIFICATIONS**

#### Receiver Options —

The following system configuration options are available in the 90478.

A — Basic Arrhythmia: High and low heart rate, asystole and ventricular fibrillation (2 leads).

**B** — Multiview<sup>™</sup> I Arrhythmia — Enables users to review trends of abnormals per minute; provides additional alarms for abnormals per minute and abnormals in a row (2 leads).

C — Multiview II Arrhythmia — 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 (2 leads).

**S** — ST segment analysis/review/trend (2 leads).

Q — Band operation, 608 to 614 MHz

T — Band operation, 1395 to 1400 MHz

V — Band operation, 1427 to 1431.5 MHz

#### **Receiver Electrical Requirements**

**Power Consumption** —  $\leq 5.0$  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-a)

Accommodates up to 8 modular receivers.

# **Housing Physical Dimensions**

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)

## **Receiver Housing Power Requirements**

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

#### **ENVIRONMENTAL REQUIREMENTS**

#### Operating —

Temperature: 50° to 104° F (10° to 40° C) Humidity: 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: 100% (non-condensing)
Altitude: -500 to 40,000 ft (-151.5 to

12,121.2 m)

Water Resistance:

Meets EN60529 IPX1

#### **REGULATORY APPROVALS**

All models are ETL listed and meet UL544 or UL2601-1 standard for electrical safety; approved by CSA; Models 91341, 91343, 90347, and 90478, approved by FCC and Industry Canada (RSS - 210, 608-614 MHz operation only).

## **ACCESSORIES**

Please refer to the Spacelabs Medical Supplies Catalog for availability of ECG lead wires and electrodes, blood pressure cuffs, and SpO<sub>2</sub> sensors from Spacelabs Medical.

91341/91343/91347 Transmitter Pouch **Part Number:** 015-0500-00

DIN Standard Safety ECG Lead Wire Set

(5 wire) 25.2-inch snap Part Number: 012-0605-00 Receiver Housing Protective Cover Part Number: 200-0180-00

Whip Antenna (UHF) 608 to 614MHz Part Number: 117-0040-00

Belt Clip

Part Number: 344-0020-00 SpO<sub>2</sub> Adapter Cable (Nellcor) Part Number: 700-0014-00 ABP Telemetry Adapter Cable Part Number: 700-0015-00

ABP Pouch

Part Number: 015-0501-00

ABP Shoulder Strap

Part Number: 016-0262-00

**ABP Waist Belt** 

Part Number: 016-0080-00

#### **SPECIFICATIONS**

ABP Report Management System Part Number: 90121ABP Report Management System Adaptor Cable Part Number: 012-0097-02

ABP Adult Adapter Assembly Part Number: 714-0017-00

Nellcor SpO<sub>2</sub> Sensor Accuracy and Sensor

**Selections** 

Nellcor Reusable SpO<sub>2</sub> Sensors —

Finger Clip (DS-100A) (P/N 690-0003-00) 70–100%,  $\pm 3\%$  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 SpO<sub>2</sub> Sensors —

Adult (N-25) (P/N 690-0006-00) 70–100%, ±2% absolute saturation

Neonatal (N-25) (P/N 690-0006-00) 70–100%, ±3% 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

Infant (I-20) (P/N 690-0002-00) 50–69%, ±3% absolute saturation 70–100%, ±2% absolute saturation Ultraview Digital Telemetry 91341, 91343, 91347, 90478, 90479-A

Table 1: Transmitter Battery Service Life<sup>1</sup> (hours)

Battery Type	9 Volt Alkaline (ANSI/NEDA 1604A)					9 Volt Lithium (ANSI/NEDA 1604LC)				
Load Con- ditions <sup>2</sup>	ECG Only	ECG and Con- tinuous SpO <sub>2</sub>	ECG and 2 minute Episodic SpO <sub>2</sub>	ECG and 5 minute Episodic SpO <sub>2</sub>	ECG and 30 minute Episodic SpO <sub>2</sub> and NIBP	ECG Only	ECG and Con- tinuous SpO <sub>2</sub>	ECG and 2 minute Episodic SpO <sub>2</sub>	ECG and 5 minute Episodic SpO <sub>2</sub>	ECG and 30 minute Episodic SpO <sub>2</sub>
91343	48	24	36	38	40	120	60	100	104	106
91341/47	52	Not Applicable	Not Applicable	Not Applicable	Not Applicable	132	Not Applicable	Not Applicable	Not Applicable	Not Applicable

Operational service life (in hours) assuming a new alkaline battery (minimum 580 mAH capacity) or lithium battery (minimum 1200 mAH capacity) used until the local low battery indicator begins to flash.

Medical telemetry spectrum allocations may be assigned to frequencies already allotted to other priority users. This means that telemetry operations may be exposed to radio frequency interference that may disrupt or impede telemetry patient monitoring. Additionally, medical telemetry spectrum allocations may be changed by government action and Spacelabs Medical accepts no responsibility for such changes, including the possibility that the product may not operate in the modified permissible spectrum ranges other than those expressly set forth in Spacelabs Medical's published product data sheets. Spacelabs Medical cannot, and does not, guarantee interference-free telemetry operation.

NIBP operations from a 90217 ABP Monitor sending readings to the 91343 Multi-parameter telemetry transmitter. The 90217 ABP monitor will inflate a standard size adult cuff at least 240 times with alkaline batteries.

Ultraview Digital Telemetry 91341, 91343, 91347, 90478, 90479-A

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