Spacelabs medical

A Division of Instrumentarium

TECH PUBS DRAFT

Ultraview® Digital Telemetry

91341 / 91343 / 91347

Operations Manual

071-0774-00 Rev. A

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CAUTION:

- **US Federal law restricts the devices documented herein to sale by, or on the order of, a physician.**

Spacelabs Medical is committed to providing comprehensive customer support beginning with your initial inquiry through purchase, training, and service for the life of your Spacelabs Medical equipment. If you need our help along the way, we offer these guidelines for fast, efficient response.

Acquiring Equipment

Sales Representative 800-522-7025 (U.S.A.) or call your local office	To discuss your monitoring or clinical information needs, to schedule product demonstrations, to order equipment, or to schedule in-service education
Delivery Information 800-251-9910 (U.S.A.) or call your local office	To find out when you can expect delivery of your Spacelabs Medical equipment
Supplies Products 800-223-6467 (U.S.A.) or call your local office	To order compatible supplies and accessories for your equipment

Getting Started

Sales Representative 800-522-7025 (U.S.A.) or call your local office	To arrange in-service education sessions

Answering Other Needs

Clinical Applications 800-522-7025 (U.S.A.) or 425-882-3700 or call your local office	To answer specific questions on arrhythmia products and clinically related issues
First Call℠ National Dispatch Center 800-522-7025 (U.S.A.) 800-942-7968 (Canada)	To call for service or to contact your assigned customer service representative
Technical Support - Monitoring/Anesthesia 800-522-7025 (U.S.A.) or 425-882-3700 or call your local office	For technical support of all Ultraview® Care Network™ monitoring products and anesthesia products
Technical Support - Intesys Clinical Information Systems 800-210-0247 (U.S.A.) or 425-882-3700 or call your local office	For technical support of BirthNet®, Caremaster®, Chartmaster®, QuIC, and WinDNA® products
Service Parts Department 800-547-8805 (U.S.A.) or 425-867-2039 or call your local office	For parts ordering and pricing information
Service Training Department 800-251-9910 (U.S.A.) or call your local office	To arrange training of hospital biomedical and anesthesia personnel
Regional Service Manager 800-522-7025 (U.S.A.) 800-942-7968 (Canada) or call your local office	To obtain answers to general questions concerning service issues and service contracts

Contacting Your Local Offices Outside the U.S.

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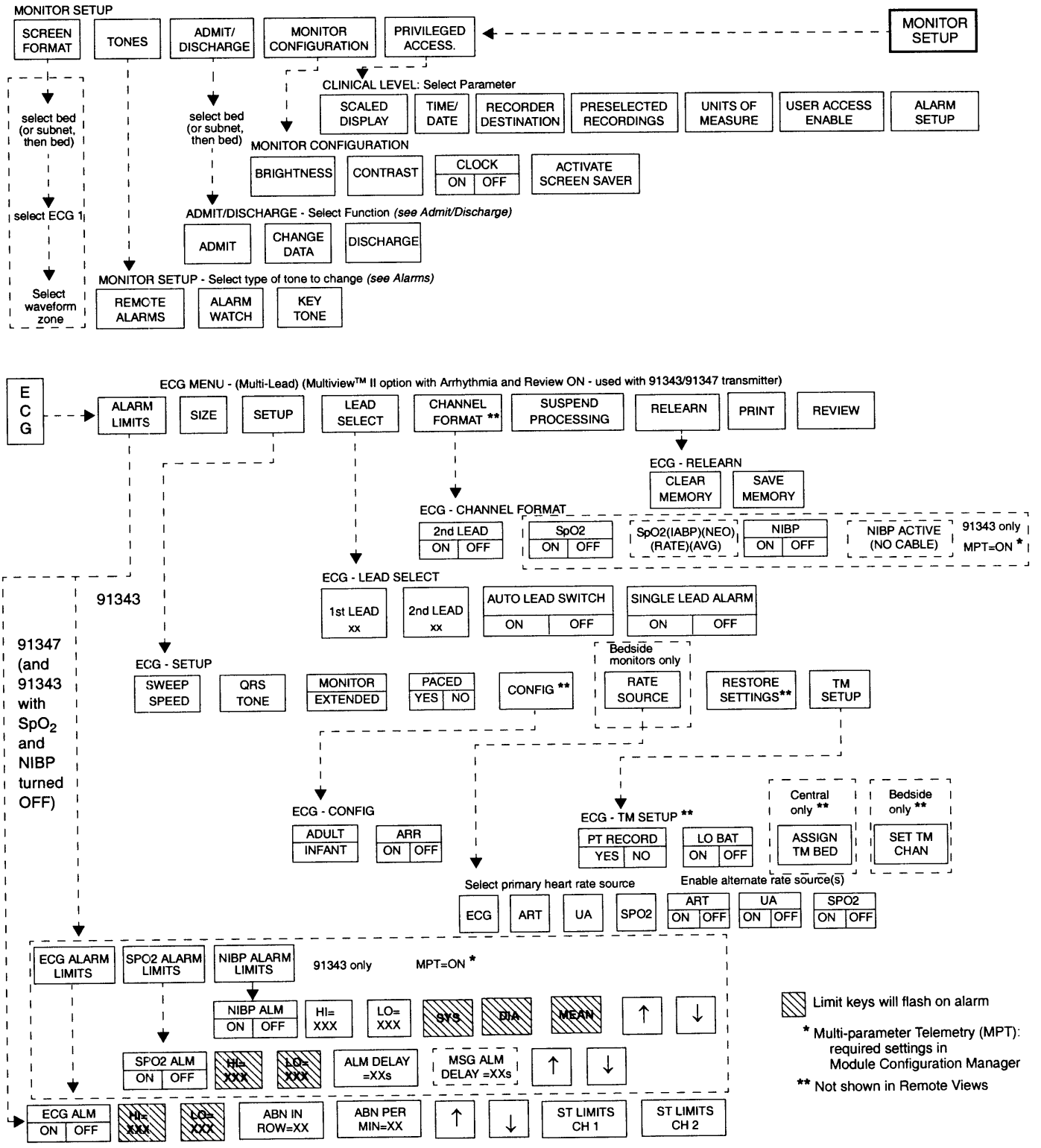

- *Based on features purchased, more or fewer keys may appear here than on your menu screens.*

Introduction

Contents

Overview

The 90478 digital telemetry receiver module, when used in conjunction with Spacelabs Medical telemetry transmitters, an Ultraview or PCMS™ monitor, and 90479-A modular receiver housing, provides continuous monitoring of electrocardiographic signals in order to detect abnormal cardiac rhythms, including asystole, ventricular fibrillation, and ventricular tachycardia. In addition, when used with the 91343 digital telemetry multi-parameter transmitter and the 90217 Ambulatory Blood Pressure (ABP) monitor, monitoring of electrocardiographic signals is augmented by the availability of continuous or episodic SpO_2 measurements and episodic noninvasive blood pressure (NIBP) measurements.

- *Spacelabs Medical's telemetry equipment complies with Part 15 and Part 95 of the FCC Rules; with RSS-210 of Industry Canada; and with requirements of other national spectrum management authorities. Repeated here are operational cautions for biomedical telemetry from the FCC Rules (47CFR15.242(f)):*

  "Biomedical telemetry devices must not cause harmful interference to licensed TV broadcast stations or to other authorized radio services, such as operations on the broadcast frequencies under subpart G and H of part 74 of this chapter, land mobile stations operating under part 90 of this chapter in the 470-512 MHz band, and radio astronomy operation in the 608-614 MHz band. (See section 15.5). If harmful interference occurs, the interference must either be corrected or the device must immediately cease operation on the occupied frequency. Further, the operator of the biomedical telemetry device must accept whatever level of intereference is received from other radio operations. The operator (health care facility) is responsible for resolving any interference that occurs subsequent to the installation of these devices."

- *Medical telemetry equipment is only for installation and use in hospitals and health care facilities. It is not permitted for use in vehicles that operate outside of the medical facility premises. The user of this equipment is not authorized to make any changes or alterations that could compromise the national certifications.*

- *Operation of telemetry equipment in the Wireless Medical Telemetry Service (WMTS) and in authorized spectrum of each country, may be geographically restricted by government regulation. A Spacelabs Medical Field Service Engineer can assist in evaluating if a hospital's location requires coordination with a protected radio astronomy observatory or other protected government site.*

WARNING:

- ***Changes or modifications not expressly approved by Spacelabs Medical will void the user's authority to operate the equipment.***

Intended Use

As an option, on adult patients, additional abnormal cardiac rhythms, such as ventricular runs, tachycardia, and ST segment deviations, can be detected. The Ultraview Digital Telemetry System also provides a means for the episodic monitoring of NIBP signals to detect abnormal events such as high and low blood pressure. Finally, it provides a means for both continuous and episodic monitoring of pulse blood oxygen saturation signals to detect oxygen desaturation caused by abnormal pulmonary/circulatory functions.

- *Episodic monitoring of NIBP values and continuous and episodic monitoring of blood oxygen saturation values are only supported in conjunction with ECG monitoring. SpO2 and NIBP alarms are inhibited by ECG leads-off condition.*

The Spacelabs Medical 91341, 91343, and 91347 Ultraview Digital Telemetry Systems are intended for use with either adult or neonatal patients in a hospital environment. When the NIBP option is selected in the 91343 configuration, the NIBP feature is to be used with adult patients only.

WARNING:

- ***The Ultraview Digital Telemetry transmitters are contraindicated for use with other medical instrumentation (e.g., respiration monitors using impedance pneumography, electrocautery, etc.) that source electrical current through the patient. Further, telemetry monitoring is contraindicated for the Operating Room environment.***

Transmitters

The transmitter is a small, battery-powered device carried by the patient that monitors ECG activity and SpO_2/NIBP (91343 only) data, and transmits this information to the telemetry receiver module.

- The 91341 transmits two leads of ECG and uses up to five lead wires. One or two leads may be displayed.
- The 91343 and 91347 transmit four leads of ECG and use up to five lead wires. However, only two leads may be displayed simultaneously.
- The 91343 is also capable of transmitting numerical NIBP and SpO_2 data. This information is displayed simultaneously with that of the ECG waveform data.

Each telemetry channel requires its own transmitter operating on a unique radio frequency. Channel receivers are tuned from the Ultraview monitor touchscreen 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 Field Service Engineer.*

WARNING:

- ***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 during the life of this equipment. You are urged to regularly consult with applicable local and federal regulatory agencies (e.g., FCC, FDA, etc.) regarding the locations and frequencies of other spectrum users in your geographic area. A Spacelabs Medical field service engineer may be able to assist you in reconfiguring your equipment frequencies to reduce the risk of interference. Spacelabs Medical cannot, and does not, guarantee interference-free telemetry operation.***

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 connected to the transmitter. Lead wires that are poorly connected to the patient (including compromised electrode connections) are locally detected and identified with flashing indicators at the ECG patient input connector. A patient-operated RECORD button initiates an ECG strip at the system printer, if this feature is enabled at the central or bedside monitor.

CAUTION:

- **This device has a limited bandwidth range of .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 ±4 mV, which may render the device vulnerable to saturation by ECG signals with amplitudes higher than 4 mV.**
- **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.**
- **Patients should not use any type of electronic equipment (e.g., portable radios, cellular telephones, pagers, personal computers, etc.) while connected to any medical electronic device without an on-site evaluation by the biomedical engineering staff.**
- **Use of two-way radio equipment and other personal communication devices must be evaluated on-site to assess the potential for disruption of monitoring.**

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

Transmitter Batteries

A 9-volt alkaline battery is recommended for standard use in the digital telemetry transmitter. A 9-volt lithium battery 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 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 approximately 7.0 volts. When this message appears, the transmitter has approximately three hours of operating time left, depending on transmitter type, selected options, and the type of battery.*
- *When the battery level falls below approximately 7.0 volts, the low battery LED on the transmitter will flash once every 15 seconds. When the battery level falls below 6.0 volts, the low battery LED will flash once every two seconds. When the battery level falls below 5.5 volts, the SpO_2 and NIBP functions will shut down and **???** will display for related vital signs measurements. The **LOW BATTERY** message may appear after the low battery LED on the transmitter begins to flash.*

Battery Disposal

The 91341, 91343, and 91347 Ultraview Digital Telemetry transmitters are operated by 9-volt primary (non-rechargeable) batteries that must be properly disposed when discharged. The batteries specified may be of either alkaline or lithium chemistry. Attempting to recharge these batteries is not recommended and can result in leaking, venting, or explosion.

Follow the battery manufacturer's recommended handling procedure for both types of batteries. Collect and transport the batteries in a manner that prevents short circuit, compacting, mutilation, or any other physical abuse or electric handling that would destroy their physical integrity. Exposure to high temperatures or fire can cause the batteries to leak, vent, or explode.

Disposing of used batteries may be subject to national, state/provincial, and/or local regulation, which varies depending on jurisdiction.

The recommended disposal procedure for alkaline batteries is to transport them to a hazardous waste landfill. Since these batteries may not be classified as hazardous waste, they may be transported to the disposal facility as non-hazardous waste.

The recommended disposal procedure for lithium batteries is to transport them as hazardous waste to a hazardous waste facility. If the batteries are physically sound, disposal of these discharged batteries in a hazardous waste landfill may be permissible. If the batteries are leaking, cracked, opened, vented, or otherwise not physically sound, they must be transported to a qualified hazardous waste facility.

Digital Telemetry Receiver Module

The 90478 telemetry receiver module plugs into a bedside, central, or transport monitor, or into a digital telemetry module housing. The receiver module receives patient vital signs data from the transmitter. This information is reconstructed by the receiver module, displayed on the monitor, and analyzed.

For more information, refer to *SpO2 (91343 only)* on page 3-1, and *NIBP (91343 only)* on page 4-1. Also refer to the *ECG, Arrhythmia,* and *ST Analysis* chapters in the *UCN Operations Manual.*

WARNING:

- ***Telemetry systems may be more susceptible to interference than hardwired systems, which may impact signal quality.***
- ***Operation of hand-held, wireless telephone equipment (e.g., cordless telephones, cellular telephones) near telemetry systems may cause interference and should be discouraged. While personal communication devices are turned on, a separation of > 6.5 feet (> 2 meters) should be maintained between personal communication devices and interior walls, the patient cables, and any electronic medical device to which the patient may be connected. Patients should not use any type of electronic communication equipment while connected to any electronic medical device without an on-site evaluation by the biomedical staff. Two-way radio equipment and other personal communication devices must be evaluated on site to determine if additional space limitations are needed.***
- ***Do not install a telemetry receiver module into a bedside that is currently equipped with any other ECG module, hardwired or telemetry (or SpO_2 module or NIBP module, if the 91343 is operating with that specific receiver module). Doing so may cause inaccurate patient data displays at remote monitors.***

Digital Telemetry Receiver Housing

The telemetry receiver 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. Operating the system without AC mains power is limited to ten minutes of battery backup time.

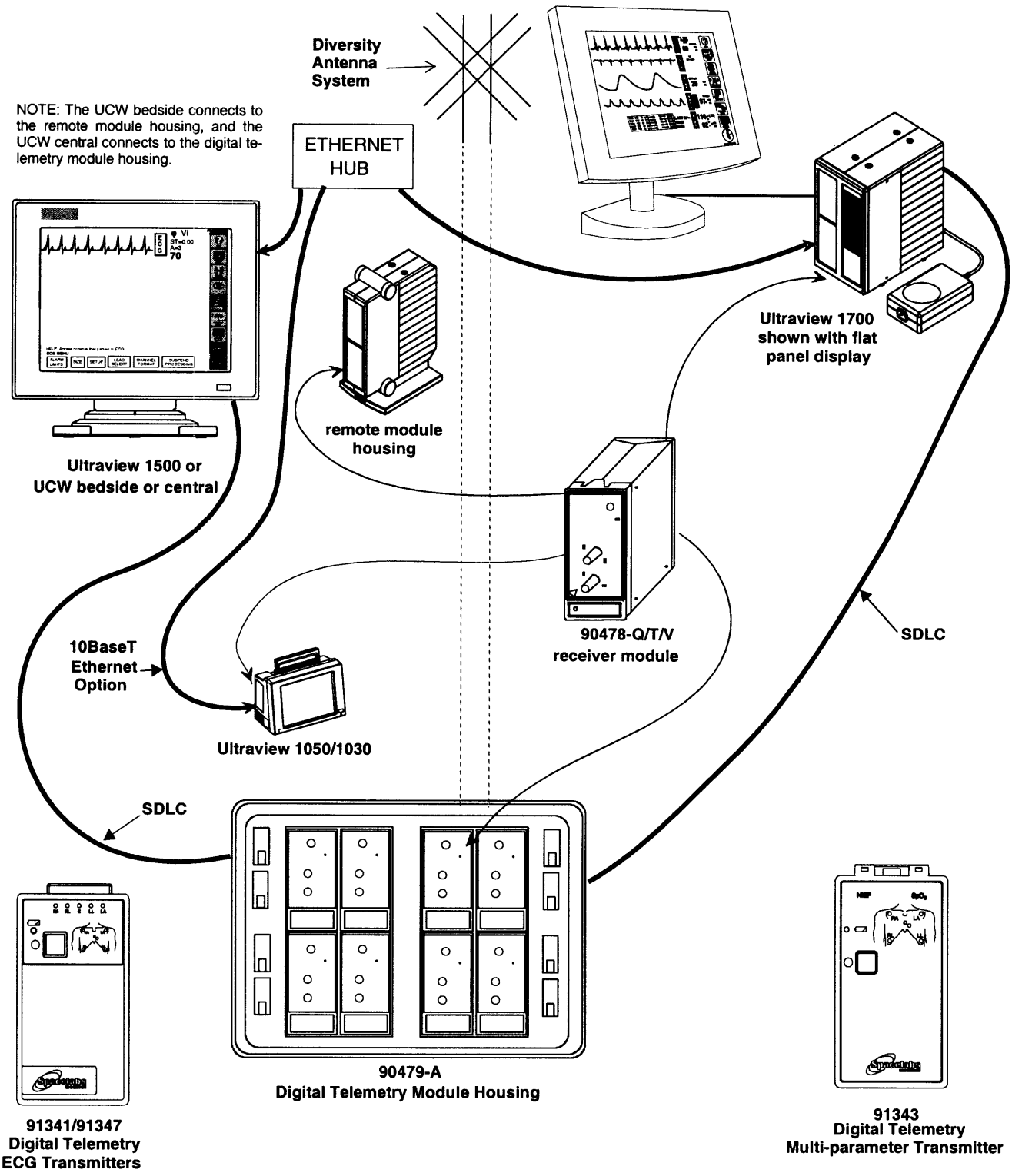

Figure 1-1: Ultraview Digital Telemetry System

Cleaning

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

To clean the transmitter, use only the following agents.

- Mild soap and water solution
- U.S. Pharmacopoeia (USP) green soap
- Sodium hypochlorite solution (1:10 dilution of household bleach in water)
- Phenolic germicidal detergent solutions (1% aqueous solutions)
- Isopropyl alcohol solution (70%)

Assigning a Telemetry Channel

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

1 Touch key label that matches transmitter's frequency.
2 Select bed/room number for transmitter channel.

To set up the central for ECG (MPT=OFF) (UCW and 1700):

1 Touch MONITOR SETUP.
2 Touch SCREEN FORMAT.
3 Select subnet and bed/room number.
4 Select ECG and then desired zone.

Telemetry transmitters have preassigned channel frequencies. This channel number is identified on the back of the case. Refer to the *Ultraview Digital Telemetry Service Manual* (P/N 070-1135-00) for information on assigning a new telemetry channel for the transmitter.

To receive this telemetry channel, one of the receivers in the telemetry receiver housing must be tuned to its assigned frequency.

- *Tuning telemetry transmitters must be performed by a qualified service person to avoid channel duplication.*
- *Tuning telemetry receiver modules to transmitter channels at the central monitor must be done by a qualified service person. This capability is only supported for the locally hosted patient monitor and is not accessible through remote views.*
- *Your central monitor 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 unassign or reassign them. Refer to the* Module Configuration Manager *chapter of the* UCN Operations Manual.

Tuning a Receiver for a Bedside

To tune a receiver module at bedside:

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.

The central monitor must be tuned by a qualified service person, but the bedside monitor may be tuned using the ECG TM SETUP menu. You can 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 using UHF band operation. For alternate band operation, or if operating in another country, you must select the appropriate frequency band using the Module Configuration Manager.*

Entering Patient Information

To admit a patient:

1 Touch MONITOR SETUP.
2 Touch ADMIT/DISCH.
3 Select subnet (UCW and 1700 only).
4 Select bed/room number for channel.
5 Touch ADMIT.
6 Select YES.
7 Use keyboard to enter patient info (UCW and 1700 only).
8 Select ID, NAME, HEIGHT, WEIGHT, or BSA, UV1050/1500 only).
9 Enter data using pop-up keypad or keyboard (UV1050/1500 only).
10 Touch ENTER.
11 Repeat steps 7 - 10 until all information has been entered.
12 Touch ACCEPT (UCW and 1700 only).

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.*

Discharging a Patient

To discharge a patient:

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

A patient is discharged by first removing the battery from the 91341/43/47 Ultraview Digital Telemetry Transmitter. The monitor displays the squelch waveform followed by the message INTERMITTANT SIGNAL LOSS after a short delay. An alarm condition is displayed on the monitor because of the signal loss.

The message IS SIGNAL LOSS PERMANENT? appears with keys labeled YES and NO in the waveform zone.

- Touch YES to indicate that the signal loss is permanent.
- Touch NO to cancel the discharge operation.

- *This message may also appear on remote views, but the YES/NO control keys are only available at the locally hosted patient monitor and are not supported for remote views.*

The next message displayed is DISCHARGE THE PATIENT?.

- Touch YES to continue the discharge process.
- Touch NO to cancel the discharge operation.

- *This message may also appear on remote views, but the YES/NO control keys are only available at the locally hosted patient monitor and are not supported for remote views.*

The monitor displays PURGES DATA-ARE YOU SURE?

- Touch YES to discharge the patient and erase all patient data. The intermittent signal loss alarm is then cancelled.
- Touch NO to cancel the discharge operation and cause the message IS SIGNAL LOSS PERMANENT? to appear in the waveform zone.

- *This message may also appear on remote views, but the YES/NO control keys are only available at the locally hosted patient monitor and are not supported for remote views.*

WARNING:

- ***During INTERMITTANT SIGNAL LOSS message activation, the display of SpO_2 and NIBP data is disabled.***

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 indicated by a triangular waveform that replaces the normal ECG waveform and 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 signal loss, the IS SIGNAL LOSS PERMANENT? message appears.

- Select NO to suspend alarm tones.
- Select YES to display the message DISCHARGE THE PATIENT?
  a. Select YES to display the message PURGES DATA-ARE YOU SURE?
  b. Select YES to discharge the patient from the system and purge all data for that patient.
  c. Selecting NO at any point in this sequence returns you to the previous option.

- *Acknowledging signal loss can only be performed at the locally hosted patient monitor and is not supported for remote views.*

Setting Battery Status Alarms

To control low battery alarms:

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

The telemetry battery alarm tone, and a LOW BATTERY message in the ECG zone involved, alerts you to a low battery condition in the transmitter. You may 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

To control transmitter's Patient Record function:

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

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.

- *This control on the Patient Record function is only supported at the locally hosted patient monitor and is not supported for remote views.*

Telemetry Alarm Message Summary

INTERMITTENT SIGNAL LOSS

The intermittent signal loss message indicates that the patient may be out of antenna range, or the battery is depleted. Return the patient into antenna range. Check that the battery is functioning properly.

LOW BATTERY

A Low Battery Message indicates that the battery is weak. After this message appears, the battery has approximately three hours of useful life left (depending on the type of battery used). Install new battery.

SIGNAL INTERFERENCE

The Signal Interference message indicates, via the displayed triangle squelch waveform, that an interfering signal has been detected.

PERMANENT SIGNAL LOSS

The Permanent Signal loss message indicates that no RF signal is being detected.

Accessories

Refer to the *Spacelabs Medical Supplies Products Catalog* for availability of accessories. Some of the more commonly used accessories are listed below.

Digital Telemetry Accessories

91341/91343/91347 telemetry transmitter pouch	015-0500-00
Belt clip	344-0020-00
Receiver whip antenna, 608 - 614 MHz (WMTS)	117-0040-00
Receiver housing protective cover	200-0180-00

ECG Accessories

DIN standard safety lead wire set, 5 wire	012-0605-00
Adult general purpose electrode	015-0097-01
Holter/stress disposable electrode	392015-001

SpO_2 Accessories

Nellcor SpO_2 adapter cable	700-0014-00
Nellcor SpO_2 sensors Adult/Neonatal (N-25)	690-0006-00
Pediatric (P-20)	690-0007-00
Adult disposable (D-25)	690-0001-00
Finger clip (DS-100A)	690-0003-00
Nasal (R-15)	690-0005-00
Oxiband A/N	690-0004-00
Oxiband pediatric/infant reusable sensor P/I	690-0039-00

NIBP Accessories

ABP adapter cable	700-0015-00
ABP Pouch	015-0501-00
ABP shoulder strap	016-0262-00
Cuff assembly, child (13-20 cm) with hose	015-0118-01
Cuff assembly, small adult (17-26 cm) with hose	015-0067-01
Cuff assembly, adult (24-32 cm) with hose	015-0068-02
Cuff assembly, large adult (32-42 cm) with hose	016-0077-01
Cuff assembly, extra-large adult (38-50 cm) with hose and cuff support harness	016-0109-01
ABP Report Management System	90121

ABP Report Management System Adaptor Cable	012-0097-02
90121 ABP Report Management System Operations Manual	070-0529-xx
90207/90217 ABP Monitors Operations Manual	070-0137-xx
Ultraview Care Network Operations Manual	070-1001-xx