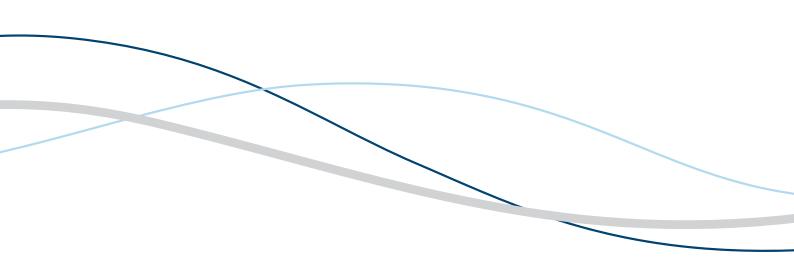




## Telemetry Transmitter 96281-A, 96281-B, 96281-C



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- the electrical installation of the relevant room complies with the requirements of the standard in force, and
- the equipment is used in accordance with the operations manual.

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Spacelabs Healthcare is committed to providing comprehensive customer support beginning with your initial inquiry through purchase, training, and service for the life of your Spacelabs Healthcare equipment.

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### Caution:

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



Before use, carefully read the instructions, including all warnings and cautions.



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## Introduction

Spacelabs Healthcare patient monitoring systems demonstrate an ongoing commitment to innovation that supports decision-making and enhances patient care.

Spacelabs Healthcare networking features support seamless data acquisition and data exchange across the medical enterprise, addressing the need for continuous information management. These powerful tools help you care for patients more efficiently by providing both local and remote access to patient data.

### **About This Manual**

This manual provides instruction for specific features of the Spacelabs Healthcare AriaTele™ Telemetry Transmitter (96281). It does not address system issues such as antenna infrastructure, receivers, central monitor or central station. Refer to the customer documentation for your specific telemetry receiver for information on antenna infrastructure. Refer to the customer documentation for your central monitor for information on the central monitor or station in use with the telemetry transmitter.

### Conventions Used in This Manual

Some of the formatting conventions used in this manual are included in the list that follows.

- For manuals viewed in PDF format, reference links are blue and italicized. Blue italicized typeface is a link to additional information in the manual. Hover the mouse over the blue text and click to show the topic. Reference links are located throughout the manual, including the Table of Contents.
- Non-blue italicized typeface are references to information outside this manual. They may indicate references to other manuals or information which is available in another form, as

identified by a title and/or a part number. Non-blue italicized typeface may also refer to error or status messages that show on the host monitor.

- **Bold** typeface indicates text labels, phrases, or titles that show on an LCD or display which are part of a Spacelabs Healthcare software application.
- **Bold** typeface may also indicate the formal name of graphical user interface, such as an icon or control, but which does not include a text label or title.
- Terms that are ALL CAPITALIZED may represent user interface such as a key label or menu, or a status or error message on a host monitor.
- Numbered steps are presented to accomplish a task. Some steps may conclude in a step result—unnumbered, indented text. Step results are shown in gray typeface. For an example of task steps, click the cross-reference To send a recording to the central monitor or station on page 4-11.
- Warnings, cautions, and notes are listed in the priority of the information and formatted specifically as shown below. Warnings are of the highest priority and notes are not as serious as the warnings and cautions.

#### Warnings:

Warnings indicate potentially harmful conditions that may lead to injury or death.

#### Cautions:

Cautions indicate conditions that may lead to damage to or malfunction of the device.

#### Notes:

Notes alert the user to relevant facts and conditions.

## Overview of the Telemetry Transmitter (96281-A/ 96281-B/96281-C)

When worn by a patient, the 96281 telemetry transmitter acquires ECG data through electrodes attached directly to the patient's body. Additionally, the 96281-C telemetry transmitter can acquire SpO<sub>2</sub> data through sensors attached to the patient's body. It transmits acquired data to the telemetry antenna infrastructure for processing by a telemetry receiver. This transmitted data may then show on a central station or bedside monitor. Refer to About the Transmitters on page 2-1 for more detailed information about each telemetry transmitter model. The 96281 telemetry transmitter does not indicate any alarm conditions. Alarms are configured, generated, and activated within the receiver-side components of the Ultraview System only.





#### Note:

SpO<sub>2</sub> functionality is only available on the 96281-C telemetry transmitter.

### Manufacturer

The 96281 telemetry transmitter is manufactured by:

Spacelabs Healthcare 35301 SE Center Street Snoqualmie, WA 98065 U.S.A.



## Relationship to Other Systems

The 96281 telemetry transmitter is related only to Spacelabs Healthcare monitoring systems. Data collected by the transmitter may be interfaced from the monitoring system to a hospital clinical information system.

The telemetry transmitter is compatible with the list of receivers that follow:

 Digital Telemetry System Receiver (90478) and Receiver Housing (90479-A, 90479-B, 90479-C)

Refer to *Patient Monitoring Operations Documents* (P/N 084-1101-xx) and to the *Spacelabs Healthcare Service CD* (P/N 070-0700-xx) for information relating to the 90478 and 90479 digital telemetry systems.

The 90478 receiver interacts with the Ultraview SL 91387-38 or 91387-39 central monitor, and with Ultraview SL patient monitors.

#### Note:

Not all products are available in all locales. Check with your local Spacelabs Healthcare representative.

### Intended Use

The Spacelabs Healthcare AriaTele Telemetry Transmitter (96281), when used in conjunction with a Spacelabs Healthcare Ultraview patient monitor and telemetry receiver, provides a means for the continuous collection and monitoring of electrocardiographic (ECG) signals in order to detect abnormal cardiac rhythms, including lifethreatening events such as high and low heart rates, asystole and ventricular fibrillation. Optionally, on adult patients, additional abnormal cardiac rhythms such as ventricular runs, tachycardia and ST-segment deviations are detected.

The 96281 also provides a means for continuous collection and monitoring of SpO<sub>2</sub>.

The 96281 provides an optional display intended to allow clinicians a means to view the  $SpO_2$  and pulse rate at the patient's side. The display also provides a snapshot view of the ECG to allow the clinician to view the patient's ECG rhythm and quality of signal.

The 96281 is intended for use with either adult, pediatric or neonate populations in a healthcare facility by, or on the order of, a physician. It is not intended for home use.

### Indications for Use

The 96281-A and 96281-B telemetry transmitters are indicated for ECG monitoring of adult, pediatric and neonatal patients. The 96281-C telemetry transmitter is indicated for ECG and  $SpO_2$  monitoring of adult, pediatric and neonate patient populations.

## Warnings, Cautions, and Notes

This chapter includes warnings, cautions, and notes specifically related to digital telemetry. Refer to the ECG chapter in the *Clinical Parameters Operations Manual*, P/N 070-2113-xx, for warnings and cautions and cautionary disclosures related to ECG. Refer to the product specifications chapter for warnings and cautions and cautionary disclosures that apply to electrodes and leadwires, defibrillators (including automatic implantable cardiac defibrillators), pacemakers, electrosurgical activity, several physiological parameters, or to the monitoring system itself.

Obey these warnings and cautions to avoid injury or death to individuals or damage to equipment.

#### Warnings:

- Review the device prior to each and every procedure. If it shows signs of abuse then either make sure the device is repaired in an appropriate manner, serviced, or retired from use
- Medical telemetry spectrum allocations may be assigned to frequencies already allotted to other priority users. Radio frequency interference from other products 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) regarding the locations and frequencies of other spectrum users in your geographic area. A Spacelabs Healthcare field service engineer may be able to assist you in reconfiguring your equipment frequencies to reduce the risk of interference. Spacelabs Healthcare cannot, and does not, guarantee interference-free telemetry operation.





- Telemetry systems may be more susceptible to interference than hardwired systems; this may impact signal quality.
- Do not use any transmitter that has been compromised by liquid ingress. If fluid has collected in the battery compartment, clean and dry it before use. If the transmitter has been immersed in liquid, it must be thoroughly dried before use. Not doing so may prevent the transmitter from working properly. If the SpO<sub>2</sub> sensor has been immersed in liquid, it should be dried and inspected for proper operation and replaced if necessary.
- The transmitters do not currently support inhibition of their pacer detection functionality. Since Left Ventricular Assist Devices (LVADs) can generate electromagnetic noise having similar characteristics to pacemaker artifact, users should pay particular attention to ECG traces acquired using these transmitters when an LVAD is in use.
- Do not use the 96281 telemetry transmitter during magnetic resonance imaging (MRI) procedures. MRI operations will cause damage to the transmitter.
- Remove the 96281 telemetry transmitter from any patient before beginning an MRI procedure.
- Operation of hand-held, wireless telephone equipment (cordless telephones, cellular telephones) near telemetry systems may cause interference and should be discouraged. While personal communication devices are turned on, a separation of >2 meters (>6.5 feet) 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 onsite 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.
- The Spacelabs Healthcare digital telemetry transmitters are contra indicated for use with other medical instrumentation (e.g., respiration monitors using impedance pneumography, electrocautery) that source electrical current through the patient. Further, telemetry monitoring is contra indicated for the operating room environment.
- The device should only ever be used for one patient at a time.
- Opening the battery door and removing one or more of the batteries will result in the patient NOT being monitored and the ECG signal NOT being processed.
- SpO<sub>2</sub> alarms are inhibited by ECG lead-off conditions.



#### Cautions:

- This telemetry transmitter has a limited bandwidth range of 0.05 to 40 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 telemetry transmitter 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.
- Clean the transmitter case with the battery door closed. If fluid or other contaminants have collected in the battery compartment, clean and dry it before use.
- Patients should not use any type of electronic equipment (for example, portable radios, cellular telephones, pagers, personal computers) while connected to any medical electronic device without prior evaluation of that electronic equipment by the biomedical engineering staff.

#### Notes:

- Continuous monitoring of blood oxygen saturation values are only supported in conjunction with ECG monitoring. SpO<sub>2</sub> alarms are inhibited by ECG leads-off condition.
- Operation of this equipment may be subject to licensing requirements by your local telecommunications authority. Please check with your Spacelabs Healthcare field service engineer.
- Spacelabs Healthcare's telemetry equipment complies with Part 95H of the FCC Rules and 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 interference is received from other radio operations. The operator, i.e., the health care facility, is responsible for resolving any interference that occurs subsequent to the installation of these devices."
  - Installation of this telemetry device is permitted in hospitals and health care facilities only. This device shall not be operated in mobile vehicles (including ambulances and other vehicles associated with health care facilities).





- The installer/user of a transmitter operating in the band of 608-614 MHz shall ensure that it is at least 80 km from the Dominion Radio Astrophysical Observatory (DRAO) near Pentiction, British Columbia. The coordinates of DRAO are: latitude N 49° 19' 15", longitude W 119°37' 12". For medical telemetry systems not meeting this 80 km separation (e.g. the Okanagan Valley, British Columbia) the installer/user must coordinate with, and obtain written the concurrence of, the Director of DRAO before the equipment can be installed or operated. The Director of DRAO may be contacted at 250-497-2300 (telephone) or 250-497-2355 (fax). (Alternatively, the Manager, Regulatory Standards, Industry Canada, may be contacted.)
- Transmitters operating in the bands 1395-1400 MHz or 1429-1432 MHz shall not be operated in the areas of Sydney, Nova Scotia, or Gander, Newfoundland and Labrador. Please contact the local Industry Canada Office for further information.
- Transmitters operating in the bands 608-614 MHz, 1395-1400 MHz or 1429-1432 MHz comply with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.
- The user of this equipment is not authorized to make any changes or alterations that could compromise the national certifications.
- Operation of hand-held, wireless telephone equipment (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.
- Telemetry equipment is authorized to operate license exempt in the European Union's (EU) Harmonized 433 to 434 MHz Short Range Device (SRD) band. Telemetry equipment operating in this band may not cause interference and must accept interference from other devices found in the band. Many countries outside the EU also permit access to this band for qualifying devices.
- Operation of telemetry equipment in the 608 to 614 MHz bands (part of the Wireless Medical Telemetry Service (WMTS)) and in authorized spectrum of each country may be geographically restricted by government regulation.

Operation of this equipment in all U.S. WMTS bands requires coordination and registration with the FCC-designated frequency coordinator.

- Operation of telemetry equipment in the 1395 to 1400 MHz and 1429 to 1432 MHz bands (part of the Wireless Medical Telemetry Service (WMTS)) and in authorized spectrum of each country may be geographically restricted by government regulation. Operation of this equipment in all U.S. WMTS bands requires coordination and registration with the FCC-designated frequency coordinator.
- Operation of this equipment may be subject to liscensing requirements by your local telecommunications authority. Check with your Spacelabs Healthcare field service engineer.
- Users of medical telemetry equipment are cautioned that the operation of the equipment could result in harmful interference to other nearby medical devices.

### Potential Users

The potential users of the 96281 telemetry transmitter are classified into the groups that follow.

### Nurses

Nurses attach the transmitter to the patient, maintain the ECG electrodes, SpO<sub>2</sub> sensor, and generally care for the patient. They may also admit the patient to the monitoring system and monitor the patient.

### Monitor Technicians

Monitor technicians may surveil patients at a central station or monitoring room configuration. Technicians may also admit patients to the system and prepare the transmitter with fresh batteries and electrodes.

### **Biomedical Engineers**

A biomedical engineer, or biomed, may install, support, and repair monitoring systems, including telemetry. Biomeds may work directly for the hospital, for a third-party contract organization, or be a Spacelabs Healthcare Field Service Engineer (FSE).

### **Physicians**

Physicians may be common reviewers of the physiological data that is collected and subsequently presented on a monitor or at a full disclosure review station. Physicians may be responsible to treat telemetry patients, including the use of defibrillation.





### **Patients**

A telemetry patient may carry a transmitter in a gown pocket or in a pouch (the transmitter is connected to the patient by way of electrodes attached directly to the patient's body). The patient can initiate a recording by pressing the **Action** button on the front of the transmitter if it is configured for this at the central station or bedside monitor.

#### Note:

The central monitor or station may be configured to ignore messages from individual telemetry transmitter units if a patient is likely to misuse this capability. Refer to the user manuals for your central monitor or station for more information.

### **Environmental Considerations**

The hospital environment where this product is used could contain environmental conditions that may affect the product.

Since this is a wireless radio frequency (RF) device, outside interference can come from multiple sources. Even while operating within the WMTS band in North America, interference and coexistence issues may occur with other products.

The device shall be sent to a separate collection facility for recovery and recycling.

Refer to the data sheet for the *AriaTele Transmitter* (96281), P/N 061-2553-xx, for operating and storage details.

### Sources of Interference

Some potential sources of interference are included in the list that follows:

- Monitoring patients in elevators during transport to other units, or outside of the primary unit.
  - Poor transmission of signals may occur. Use a monitor with a display if elevator transport is required.
- Monitoring patients off the ward (radiology areas, for example) may result in poor reception due to antenna placement and wall construction.
  - If monitoring is necessary, the augmentation of the antenna system may be required.
- Defibrillation of a patient who is wearing the product.
- Implanted or external pacemakers associated with a patient who is wearing the product.

## Potential Sources of Damage

- The product accidentally drops onto hard surfaces, such as flooring or walls, or into sinks or toilets.
- Exposure to disinfectant and various types of cleaner.

Refer to Cleaning, Disinfecting, and Sterilization on page 5-1 for more detailed information.

### Accessories

For optimum performance, only use the device with recommended accessories. Refer to the data sheet AriaTele Transmitter (96281), P/ N 061-2553-xx, for transmitter accessories and to the Spacelabs Healthcare Supplies and Accessories Catalog for a list of suitable electrodes and supplies from Spacelabs Healthcare.

## Repairs

Transmitters that are damaged and need repair should be sent to an authorized Spacelabs Healthcare repair depot for repair, recovery, or recycling. Check with your Spacelabs Healthcare representative for locations.





## **About the Transmitters**

## Telemetry Transmitters (96281-A, 96281-B, 96281-C)

The telemetry transmitters function as part of a digital telemetry system. This system consists of transmitters, diversity antennas, receiver modules, and either a receiver housing and/or a monitor. Typically a request comes from a central host monitor to obtain data from electrodes and/or remote sensors attached to a patient which are connected to the transmitter. The central or bedside monitor tells a receiver what channel to begin listening on—one that matches the transmitter on the patient.

Refer to the data sheet AriaTele Transmitter (96281), P/N 061-2553xx, for the options available with the 96281 telemetry transmitter. Contact your Spacelabs Healthcare representative for the complete compatibility list.







96281-A

96281-B

96281-C

The patient-worn transmitters are small battery-powered devices that monitor ECG activity and SpO2 data (96281-C only) and transmit this information to the telemetry receiver module.

Each transmitter only uses one channel. The wideband units transmit four leads; the narrowband units transmit two leads. The transmitters with a display show four leads.

A label is affixed to each transmitter with its channel number representing a unique radio frequency. Telemetry receivers are tuned from the Spacelabs Healthcare monitor touchscreen to receive the available transmitter frequencies.

All transmitters are assigned a channel number at the factory. When using telemetry, the receiver must be assigned the appropriate channel for a patient at the bedside or central monitor. Admission of the patient is done at the monitor.

### Lead Fault Indicators

The 96281 transmitter has amber indicators on the front of the transmitter case. Each indicator provides the status of its respective leadwire and flashes if the leadwire is disconnected from the skin electrode or if the skin electrode makes poor electrical contact with the patient. It is possible for all lead fault indicators to flash simultaneously if all electrodes are disconnected. In addition, all indicators may flash if the transmitter is unable to determine an ECG waveform.

Up to five standard, disposable, silver/silver chloride chest electrodes may be connected to the patient. The ECG leadwires are attached to these electrodes and connected to the transmitter.

The 96281 telemetry transmitter is designed to operate with five patient leadwires. If you choose to use only three or four patient leadwires, patient information is still processed, but a lead fault message will show on the host monitor. An optional leadwire grouper is available for use with the ECG leadwires (refer to Figure 2-2 on page 2-3).



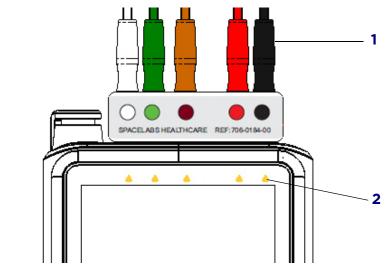


Figure 2-1 ECG leadwire connectors and lead fault indicators (96281-

- 1 Leadwire connectors
- 2 Lead fault indicators

## Optional Leadwire Grouper

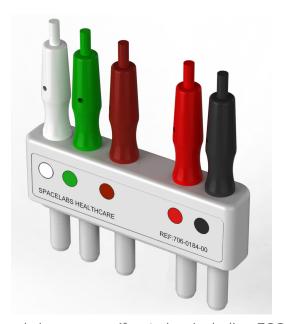


Figure 2-2 Leadwire grouper (front view including ECG connectors and color codes label)



Figure 2-3 Leadwire grouper (rear view including clip and ECG connectors)

## Labeling

### Leadwire Color Codes

Both AHA/AAMI or IEC color codes are used on the leadwires and the transmitter labeling. The color codes for your transmitter and leadwires are based on the preference in your locale. These color variations are shown on the back label of the transmitter, front of the leadwire grouper, and on the individual ECG connectors and leadwires. This is to assist in connecting the leadwires to the correct input.

- 1 Match the color of the ECG leadwire to the color label on the leadwires grouper
- 2 Match the color label on the leadwires grouper to the color label on the transmitter



### AHA/AAMI Leadwire Labels

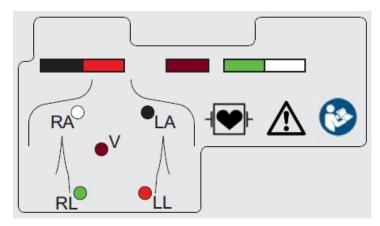


Figure 2-4 5-lead AHA/AAMI color codes label on rear of transmitter



Figure 2-5 5-way AHA/AAMI label on front of grouper

### IEC Leadwire Labels

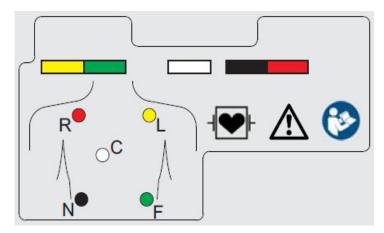


Figure 2-6 5-lead IEC color codes label on rear of transmitter



Figure 2-7 5-way IEC color codes label on front of grouper

### Telemetry Channel Label

#### Note:

"Ch." refers to the channel. The label includes a barcode on the 96281 devices.

Table 2-1 Labels for Radio Frequency Channels

Radio Frequency (RF)	Channel Label Border Color
608-614 MHz	
433-434 MHz	
1395-1431.5 MHz	

## Lead Availability

ECG lead availability depends on which electrodes are connected to a transmitter, and whether the transmitter is a Narrowband device (option N), or a Wideband device (option W).

Table 2-2 and Table 2-3 detail lead availability for narrowband and wideband transmitters, respectively, based on which electrodes are connected.

### Notes:

- · Augmented leads aVR, aVL and aVF are only available at the monitor when leads I, II, and III are all available.
- For optimum performance, the right leg electrode should always be connected.
- If an electrode is not connected, its lead fault indicators will flash on and off at the transmitter.
- If there are no leads available, all lead fault indicators will flash on and off at the transmitter.
- The headings for each electrode list the AAMI and IEC lead designations (the IEC designations are in parentheses).
- If a lead is not available, the monitor will either show a blank or switch to an alternate available lead.
- Leads are only shown on a transmitter if the transmitter includes an optional display.
- If a lead is not available, the transmitter will show a baseline trace.



• Other combinations of disconnected electrodes yield no useful data, resulting in no lead availability at either the monitor or the transmitter.

Table 2-2 Lead Availability with Narrowband transmitters (96281-xxxNx)

Conne	cted Elec	ctrodes	(X)		Available leads at the	Shown leads at the transmitter	
RA (R)	LA (L)	LL (F)	RL (N)	V (C)	monitor		
Х	X	X	X	X	II, V	I, II, III, V	
X	X	X		X	II, V	I, II, III, V	
X	X	X	Х		I, II, III, aVR, aVF, aVL	1, 11, 111	
X	X	X			I, II, III, aVR, aVF, aVL	1, 11, 111	
	X	X	Х	X	III	III	
	Х	X	X		III	III	
	X	X		X	III	III	
	Х	Х			III	III	
X		X	Х	Х	II	II	
X		Х	Х		II	II	
X		Х		Х	II	II	
X		X			II	II	
X	Х		X	X	I	I	
X	X		Х		I	I	
X	X			Х	I	I	
X	X				1	I	

Table 2-3 Lead Availability with Wideband transmitters (96281-xxxWx)

Conne	cted Ele	ctrodes	(X)		Available leads at the	Shown leads at the transmitter	
RA (R)	LA (L)	LL (F)	RL (N)	(C)	monitor		
X	Х	X	X	X	I,II,III,V, aVF, aVL, aVR	I, II, III, V	
X	X	Х	X		I,II,III, aVF, aVL, aVR	1, 11, 111	
×	X	Х		X	I,II,III, aVF, aVL, aVR	1, 11, 111	
	X	X	Х	X	III	III	
	X	Х	Х		III	III	
	X	Х		X	III	III	
X		X	Х	X	II	II	
X		Х	X		II	II	

Table 2-3 Lead Availability with Wideband transmitters (96281-xxxWx)

Connec	cted Elec	ctrodes (	(X)		- Available leads at the	Shown leads at the transmitter	
RA (R)	LA (L)	LL (F)	RL (N)	V (C)	monitor		
X		X		X	II	II	
X	X	X			II	II	
X	Х		Х	X	I	1	
X	Х			Х	I	I	
Х	Х		Х		I	I	



# ECG and SpO<sub>2</sub>

## **ECG** Overview

ECG monitoring begins when the system detects a signal through the connection of ECG electrodes or by installation of a battery into a telemetry transmitter. Please refer to the operations manual for your patient monitor for complete information on ECG and  ${\rm SpO}_2$  setup.

Telemetry ECG monitoring requires the minimum conditions from the list that follows:

- ECG electrodes must be properly attached to the leadwires.
- The leadwires must be properly attached to the telemetry transmitter.
- The telemetry transmitter must have functional batteries.
- The telemetry receiver module must be:
  - Inserted in the receiver housing that is connected to a central station, or
  - Connected to a monitor that is powered ON.
  - Configured to the same channel number as its corresponding telemetry transmitter.
  - Connected to a Spacelabs Healthcare diversity antenna.

## Patient Preparation and Electrode Application

Use silver/silver-chloride electrodes or their equivalent, and always connect all electrodes required for a particular lead. Missing electrodes may result in the loss of the ECG waveform.

#### Note:

Use only Spacelabs Healthcare-recommended electrodes. Some electrodes may polarize and create large offset potentials. This can compromise recovery time after application of defibrillator pulses. Squeeze-bulb electrodes, commonly used for diagnostic ECG recordings, may be particularly vulnerable to this effect.

Noise on ECG signals, especially noise that resembles actual cardiac waveforms, is a frequent cause of false alarms. Some of this noise may be because of electrode positioning, patient movement or intermittent signal connections (either of electrode to skin or of leadwires to electrodes). You can eliminate some of this noise (and many of these false alarms) by paying careful attention to skin preparation and electrode application.

The telemetry transmitter is color-coded to match the color of the leadwires. Table 3-1 on page 3-3 lists leadwire color and identifier codes.

## To Set Up ECG Monitoring

When attaching leadwires to the telemetry transmitter, use the color coding and/or leadwire identifier code to ensure that the correct connections are made.

ECG electrodes have a column of conductive gel that is surrounded by an adhesive surface. The condition of the electrode's gel column directly affects the quality of the ECG signal. For example, more noise appears on the ECG signal if gel is displaced (or air is trapped) when you apply an electrode to the patient. Key points to remember include:

- Before using electrodes, verify that they have not expired and that the conductive gel is not dry. Replace the electrodes if necessary.
- Always attach the electrode to its leadwire before applying the electrode to the patient (refer to Figure 3-1). Do not apply pressure directly over the electrode's gel column.
- Press firmly around the outer edge of the electrode's adhesive surface to ensure that the electrode is securely attached to the patient.
- To minimize muscle artifact, place electrodes over flat, nonmuscular areas of the body (refer to Figure 3-2). This is important for telemetry patients who are usually ambulatory.
- After electrodes and leadwires are attached, add a stress loop (a loop of leadwire taped close to its electrode) to minimize stress or pulling on the electrode itself. This will improve ECG signal quality, particularly for ambulatory patients.

#### Note:

Spacelabs Healthcare recommends that electrodes be replaced after 24 to 48 hours of use.





### To prepare the patient

- Wash the area with soap and water.
- If necessary, shave the area where you plan to position the electrodes.
- Clean the skin with alcohol.
- Dry the skin thoroughly.
- Abrade the skin.

### To apply ECG electrodes

- · Attach an electrode to a leadwire.
- Apply the electrode to the patient's skin.

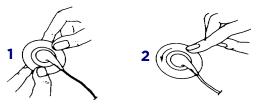


Figure 3-1 Electrode application

- 1 Attach the electrode to the leadwire.
- **2** Apply the electrode to the skin.

Table 3-1 Leadwire Color and Identifier Codes

AAMI Electrode Identifier	AAMI Color Code	Electrode Placement	IEC Electrode Identifier	IEC Color Code
RA	White	Right Arm	R	Red
LA	Black	Left Arm	L	Yellow
LL	Red	Left Leg	F	Green
RL	Green	Right Leg	N	Black
V	Brown	Chest	С	White

### Adult Flectrode Placement

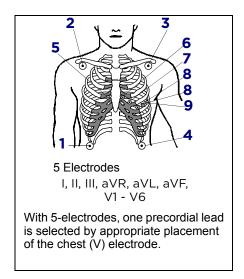


Figure 3-2 Adult electrode placement

1	RL			
2	RA			
3	LA			
4	LL			
5 - 9	V1 through V6			

#### Note:

For best ECG performance, the right leg electrode should always be connected.

## **ECG Problem Solving**

If ECG signal quality is poor (indicated by wandering baseline, excessive noise, or muscle or respiration artifact), try the solutions from the list that follows:

- Make sure that silver/silver-chloride electrodes are being used.
- Make sure that the patient's skin is properly prepared.
- Make sure that all electrodes are firmly attached and in good condition.
- Make sure that the electrodes are positioned on a flat, nonmuscular area.
- · Make sure that leadwires are properly fastened and in good condition.
- If these actions fail to resolve the problem, select a different lead.



### Lead Fault Indication

The lead fault indication messages listed here are on the central monitor/station and not the transmitter display.

The message CHECK XX (where XX identifies the failed or missing electrode) appears in the ECG waveform zone if a lead fault occurs.

If automatic lead switching is enabled, another lead is automatically selected so that monitoring is uninterrupted.

A *LEADS OFF* message appears if automatic lead switching is disabled.

### Noise Detection

A *NOISY SIGNAL* message appears in the ECG waveform zone of the central monitor/station if noise is detected. If both the first and second lead are noisy, the module suspends processing temporarily. If the noise persists for 10 seconds, the system initiates an alarm. The message and alarm cease when the noise disappears.

#### Notes:

- If monitoring is interrupted because of overload or saturation
  of the input amplifiers, including overload caused by a
  defibrillator discharge, the ECG waveform is shown as an outof-range signal accompanied by a NOISY SIGNAL or HR
  UNAVAILABLE message. If the overload or saturation
  condition persists, the ECG waveform is shown as a flat-line
  signal accompanied by an ASYSTOLE ALARM message.
- If the waveform shown does not appear noisy, but the NOISY SIGNAL message persists, check all leads for noise before calling a qualified field service engineer.

### False Alarms

Careful attention to skin preparation and electrode application, especially during setup, will reduce false alarms.

If false alarms occur, check for the issues from the list that follows:

- Excessive noise on the signal (the most common cause of false alarms). Electrodes that are placed incorrectly over muscles, or a poor lead connection, can cause significant noise when the patient moves.
- Heart rate limits set too close to patient's heart rate. Adjust the limits as necessary.

## SpO<sub>2</sub> Overview

Pulse oximetry is used to continuously and noninvasively measure functional oxygen saturation in the blood. Pulse oximetry is measured by using changes in light absorption, as the light passes over a pulsating arteriolar bed. Pulse oximetry is also used to continuously and noninvasively measure pulse rate, using an SpO<sub>2</sub> sensor.

#### Note:

SpO<sub>2</sub> functionality is only available on the 96281-C telemetry transmitter.

The pulse oximetry sensor contains two light-emitting diodes (LEDs). These LEDs emit specific wavelengths of red and infrared light, which are measured by a photo detector. The monitor shows this functional oxygen saturation as percent SpO<sub>2</sub>.

The amount of light absorbed by the arteriolar bed varies during pulsations. During systole, a pulse of arterial blood enters the vascular bed, increasing the blood volume and light absorption. During diastole, blood volume and light absorption reach their lowest point. The pulse oximeter's SpO<sub>2</sub> measurement depends on the difference between the maximum and minimum absorption (systole and diastole, respectively).

### Traditional Pulse Oximetry

### Traditional pulse oximetry is based on two principles:

- Oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry).
- The volume of arterial blood in tissue and the light absorbed by the blood changes during the pulse (plethysmography).

Traditional pulse oximetry assumes that all of the pulsations in the light absorbance signal are due to oscillations in the arterial blood volume. Therefore, the blood flow in the region of the sensor passes entirely through the capillary bed. Concentrating on the light absorption of pulsatile arterial blood eliminates the effects of nonpulsatile absorbers (such as bone, tissue, pigmentation, and venous blood), which normally absorb a constant amount of light over time.

Oxyhemoglobin and deoxyhemoglobin differ in light absorption. The amount of red and infrared light absorbed by blood can be used to calculate the ratio of oxygenated hemoglobin to total hemoglobin in arterial blood, at each of two wavelengths (such as 660 nm and 940 nm). This ratio is translated into the functional oxygen saturation  $(SpO_2)$  measurement that the monitor shows.

#### Note:

 Because SpO<sub>2</sub> measurements depend upon light from a sensor, excessive ambient light can interfere with the pulse oximeter's measurements.



- This pulse oximeter measures functional saturation, which is essentially the percentage of hemoglobin that can transport oxygen (oxyhemoglobin). Pulse oximeters do not detect significant amounts of dysfunctional hemoglobins, such as carboxyhemoglobin or methemoglobin, which cannot carry oxygen. Saturation measurements from pulse oximeters cannot be directly compared to measurements from a laboratory co-oximeter. Co-oximeters provide a fractional saturation (SaO<sub>2</sub>) value by measuring each type of hemoglobin individually. This fractional value is the ratio of oxygenated hemoglobin to all measured (oxygenated and dysfunctional) hemoglobins.
- A pulse oximeter SpO<sub>2</sub> measurement may not match the saturation calculated from a blood gas partial pressure of oxygen (PO<sub>2</sub>). The most likely reason is that the calculated saturation value was not corrected to reflect the effects of variables that alter the relationship of PO<sub>2</sub> and pH. Such variables can include temperature, the partial pressure of carbon dioxide (PCO<sub>2</sub>), 2,3-DPG, and fetal hemoglobin.

Refer to your hospital's protocols for specific instructions.

## Warnings and Cautions for SpO<sub>2</sub>

This section includes warnings and cautions specifically related to  ${\rm SpO}_2$ . Also included are cautionary disclosures that apply to electrodes and leadwires, defibrillators (including automatic implantable cardiac defibrillators), pacemakers, electrosurgical activity, several physiological parameters, or to the monitoring system itself.

#### Warning:

- A pulse oximeter should be considered an early warning device and should NOT be used as an apnea monitor. If a trend toward patient deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's condition.
- Pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. The pulse oximeter should not be used as a replacement or substitute for ECG-based arrhythmia analysis.
- Carboxyhemoglobin may erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes or any substance containing dyes that change usual arterial pigmentation may cause erroneous readings.
- Inaccurate measurements may be caused by:
  - Significant levels of dysfunctional hemoglobins (e.g., carboxyhemoglobin or methmoglobin).

- Intravascular dyes such as indocyanine green or methylene blue.
- Exposure to excessive illumination, such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight (exposure to excessive illumination can be corrected by covering the sensor with a dark or opaque material).
- Venous pulsations.
- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
- Do not use the oximetry sensors during MRI scanning. Induced current could potentially cause burns.
- Tissue damage can be caused by incorrect application or by wrapping the sensor too tightly for example. Inspect the sensor site as directed in the sensor directions for use to ensure skin integrity and to ensure correct positioning and adhesion of the sensor.
- · Applying an oximetry sensor incorrectly or leaving the sensor in place for too long may cause tissue damage, especially when monitoring neonates.
- Check the sensor site frequently, and do not allow the sensor to remain on one site for too long. Refer to the instructions from the sensor manufacturer for more information.
- Do not use a sensor with exposed optical components.
- SpO<sub>2</sub> functional test fixtures can not be used to assess accuracy of a pulse oximeter sensor or monitor.

### Electrodes, Leadwires, Sensors, and Sensor Cables

#### Warnings:

- Carefully route all cables between the patient and the monitor to reduce the possibility of patient entanglement or strangulation.
- Signals resulting from devices such as Implantable Cardiac Defibrillators (ICD) may momentarily blank the ECG waveform rather than show an out-of-range signal. In such cases it may not be apparent that the ICD has triggered and the condition of the patient should be checked. In all instances of the ICD being triggered, the monitor will reshow the ECG waveform within five seconds.
- ECG alarms for ventricular fibrillation and asystole remain active while the patient's rate and morphology are being learned (for example, following a lead switch or use of the RELEARN feature). ECG alarms for high rate, low rate, ventricular run, couplet, VE/minute, atrial fibrillation, pause, and PSVT are not reactivated until the learning process ends.





• To ensure against any possibility of electric shock, do not touch lead electrodes or the monitor during defibrillation.

### Electrodes, Leadwires, Sensors and Sensor Cables

#### **Cautions:**

- Visually inspect each leadwire for obvious damage and replace as needed.
- Use only patient cables and leadwires specified by Spacelabs Healthcare. Other cables and leadwires may damage the monitor during defibrillation and may also change the required input impedance and DC offset voltage, affecting performance.
- · Do not use stainless steel electrodes.
- Do not allow conductive parts of electrode leads or connectors, including the neutral electrode, to contact other conductive parts, including the ground.
- Use only patient sensors specified by Spacelabs Healthcare.
   If you use sensors other than those specified, it may degrade SpO<sub>2</sub> performance and could damage the monitor during defibrillation.
- Spacelabs Healthcare recommends the use of sensors repaired or remanufactured by the original manufacturer only.
- Never attach an SpO<sub>2</sub> sensor to 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.
   The Sensorwatch signal-strength indicator is used to identify a poorly applied sensor or a poorly chosen site. Refer to Using the Sensorwatch Feature on page 3-13 for additional information.
- Choose a site with sufficient perfusion to ensure accurate oximetry values.
- An adapter cable is required 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.

#### Note:

For cleaning and disinfecting procedures, refer to the Cleaning, Disinfecting, and Sterilization chapter of this manual.

## Setting Up SpO<sub>2</sub> Monitoring

- 1 Connect the SpO<sub>2</sub> adapter cable to the patient-worn telemetry transmitter.
- 2 Attach the sensor to the patient and connect the sensor cable to the SpO<sub>2</sub> adapter cable.
- **3** Initiate ECG monitoring on the patient monitor.
- 4 Touch ECG.
- 5 Touch CHANNEL FORMAT.
- 6 Touch SpO<sub>2</sub>/ON.

## Ensuring Accurate SpO<sub>2</sub> Monitoring

Each sensor requires site-specific application procedures. The quality of the patient's pulse oximetry measurements and pulse signals may be adversely affected by certain environmental factors, by oximetry sensor application errors, and by patient conditions. Any of these factors can interfere with the monitor's ability to detect and show measurements and may result in a loss-of-pulse condition. If the SpO<sub>2</sub> measurement does not seem reasonable, first check the patient's vital signs by alternate means and then check the pulse oximeter for proper operation.

Patients with anemia and/or significant concentrations of dysfunctional hemoglobins (such as carboxyhemoglobin, methemoglobin, and sulphemoglobin) may appear to have normal saturation values while actually being hypoxic. Further assessment, using means other than pulse oximetry, is recommended for such patients.

- For anemic patients, this condition occurs because patients have decreased arterial oxygen contents.
- For patients with dysfunctional hemoglobins (that are unable to carry oxygen), this condition occurs because less functional hemoglobin is available to carry oxygen.

#### Caution:

Hemoglobin levels below 5 g/dl may prevent the monitor from providing SpO<sub>2</sub> values.

Other patient conditions that may result in inaccurate measurements or a loss-of-signal condition during operation include:

- · Low perfusion
- Dark pigment
- Prolonged and/or excessive patient movement
- · An arterial occlusion (blocked artery) proximal to the sensor
- Venous pulsations





- Wrapping the sensor too tightly around the patient's digit or other extremity
- Placing the sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- Inflating a blood pressure cuff on the limb to which the sensor is attached

## External factors that may adversely affect the accuracy of oximetry readings include:

- High ambient lighting
- High-frequency electrical noise, such as electrosurgical units and defibrillators
- The presence of intravascular dyes, such as indocyanine green or methylene blue, or externally applied coloring, such as nail polish or pigmented creams
- The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia
- The patient is in cardiac arrest or is in shock

#### Caution:

Sources of high ambient light such as direct sunlight, surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, and infrared heating lamps can interfere with an  ${\rm SpO}_2$  sensor's performance and result in inaccurate measurements. When using  ${\rm SpO}_2$  under such conditions, this interference can be reduced by covering the application site with an opaque material and by ensuring that the sensor is properly applied.

#### Taking the actions that follow may improve SpO<sub>2</sub> performance:

- Select an application site with unrestricted blood flow.
- Do not select a site near potential electrical interference (e.g., electronic equipment, electrosurgical units, other power cords). If possible, remove these electrical noise sources from the area.
- If artificial nails or externally applied coloring agents such as nail polish are present, select another site or remove the polish/ artificial nails.
- If necessary, wipe the sensor site for 20 to 30 seconds with a 70% isopropyl alcohol pad to improve performance.
- Apply the sensor correctly, ensuring that the LEDs and the photo detector are properly aligned directly opposite each other, preferably on a site that minimizes the distance between the emitter and photodetector. Periodically check to ensure that the sensor remains properly positioned on the patient.
- Do not restrict blood flow when securing a sensor with tape.
- If high ambient light is affecting measurements, ensure that the sensor is properly applied and then cover the application site with an opaque material such as a blanket or towel. Failure to do this may result in inaccurate measurements.

• Maintain a minimum signal level above the Sensorwatch bar.

If patient movement presents a problem, one or more of the actions that follow may correct it:

- · Verify that the sensor is properly and securely applied.
- · Move the sensor to a less active site; to reduce or eliminate motion artifact, the application site should remain as immobile as possible.
- Use an adhesive sensor that tolerates some patient motion.
- · Use a new sensor with fresh adhesive backing.

## SpO<sub>2</sub> and Pulse Rate Specifications

### Displayed Range

SpO<sub>2</sub> (functional) 0% - 100% Pulse Rate (bpm) 30-240 bpm

### Resolution

SpO<sub>2</sub> (functional) 1% Pulse Rate (bpm) 1 bpm

Table 3-2 Pediatric or Adult SpO<sub>2</sub> and Pulse Rate Accuracy

Parameter	Patient Type	Signal Condition	Range	Accuracy
SpO <sub>2</sub> (functional)	Pediatric or Adult	No motion and normal perfusion	70-100 0-69	+/- 2% unspecified
Pulse Rate (bpm)	Pediatric or Adult	No motion and normal perfusion	30-240	+/- 3 bpm

Table 3-3 Neonate SpO<sub>2</sub> and Pulse Rate Accuracy

Parameter	Patient Type	Signal Condition	Range	Accuracy
SpO <sub>2</sub> (functional)	Neonate	No motion and normal perfusion	70-100 0-69	+/- 3.25% unspecified
Pulse Rate (bpm)	Neonate	No motion and normal perfusion	30-240	+/- 3 bpm



## Using the Sensorwatch Feature

The Sensorwatch feature provides a graphical presentation of the amplitude of the signal received from the sensor. It can be used to determine the best sensor site and application.



Figure 3-3 SpO<sub>2</sub> Sensorwatch bar on the 91387-38 central monitor



Figure 3-4  $SpO_2$  Sensorwatch symbol on the 96281-C telemetry transmitter.

Changes in the bar's shaded level signify changes in the patient's perfusion or changes in the application of the sensor. The horizontal line in the bottom fourth of the bar is used in Spacelabs Healthcare  ${\rm SpO}_2$  technology only and represents the minimum signal level that results in accurate saturation values.

When the shading is just below this line, the message LOW SIGNAL STRENGTH - Reposition or replace sensor appears.

- Reposition the sensor to a different site to provide better perfusion.
- Reposition the sensor to provide better contact with the skin.
   Make sure the LEDs and photo detector are properly aligned.
- Replace a defective sensor.
- Wait for the patient to warm up and for the patient's perfusion to increase.

## **Enabling and Adjusting Alarms**

## Spacelabs Healthcare Technology

Pulse oximetry alarm limits and delays are set internally based upon defined default values. Refer to the user manuals for your patient monitor for details on operating system alarms.

To enable and adjust SpO<sub>2</sub> alarms (telemetry)

- 1 Touch ECG.
- 2 Touch ALARM LIMITS.
- 3 Touch SPO2 ALARM LIMITS.
- 4 Select SPO2 ALM / ON.
- 5 Select HI=, LO=, ALM DELAY, or MSG ALARM DELAY (if present).
- **6** Use the arrow keys to adjust.

## Additional Information for Telemetry Products

When SpO<sub>2</sub> alarms are enabled, a bell symbol appears immediately after the measured  $SpO_2$  saturation percentage (%).

## Data Averaging

Data averaging is performed internally on the telemetry transmitter. The data averaging feature smooths the oximetry saturation value by averaging patient input values over several seconds.

## Telemetry

For telemetry monitoring, the heart rate for the display is obtained directly from the acquired ECG leads. In addition, the pulse rate is obtained from the SpO<sub>2</sub> parameter. SpO<sub>2</sub> pulse rate is viewable in the patient's trends and on the 96281-C telemetry transmitter.

## Heart Rate Averaging

## On-Transmitter Heart Rate Display Performance

The 96281-B and 96281-C transmitters can show the patient's heart rate when the transmitter is in view mode. The heart rate shown on the transmitter is to aid patient hook up and is indicative only; it is not for diagnostic use. The heart rate shown on the transmitter is not related to the heart rate shown on any central monitor/station. The



heart rate is calculated using the QRS complexes detected within the last five seconds on ECG data. Averaging is performed within the five second window. The heart rate shown on the screen is updated approximately every 1.8 seconds.

The on-transmitter heart rate display has been tested according to IEC 60601-2-27:2011 for:

- Tall T-wave rejection: It rejects T-waves up to 75% of the QRS complex amplitude,
- Maximum response times, to the nearest second, to step changes in heart rates:
  - 5 seconds when the heart rate changes from 80 beats per minute to 120 beats per minute.
  - 5 seconds when the heart rate changes from 80 beats per minute to 40 beats per minute.
- Heart rate accuracy and response to irregular rhythms:

The heart rates that show on the display for the four irregular rhythm test waveforms within the standard are listed in **Table 3-4**.

Table 3-4 Heart Rates for Four Irregular Rhythm Test Waveforms

Test Waveform	Heart Rate Shown On Transmitter
A1	80
A2	63
A3	119
Α4	86

### Warning:

The on-transmitter heart rate display accuracy may be affected by cardiac arrhythmias and pacemaker pulses. The heart rate shown on a central station or bedside monitor may similarly be affected. Refer to their manuals for appropriate details.

### Note:

The on-transmitter heart rate is calculated using ECG Lead II only, consequently if either RA or LL electrode is not present, then heart rate cannot be calculated and ??? will be shown on the transmitter display.

## Display Details at the Host Monitor

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.

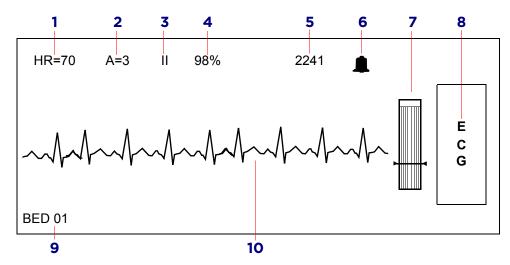


Figure 3-5 Central monitor — split view (SpO<sub>2</sub> turned ON)

### Notes:

- SpO<sub>2</sub> does not show if it is turned OFF.
- A bell symbol follows the percent (%) symbol if the SpO<sub>2</sub> alarm is enabled.
  - 1 Current heart rate
  - 2 Abnormal beats per minute counter
  - **3** ECG lead designator
  - 4 SpO<sub>2</sub> reading
  - 5 Telemetry channel number
  - 6 ECG rate alarm limits. Split-view central monitors show a bell symbol when alarms are enabled.
  - 7 Sensorwatch signal strength indicator

Shaded area (waveform index, WFI) expands up proportionally to signal strength; horizontal line indicates minimum signal level.

No shading (lowest waveform index) corresponds to no detected signal strength or a faulty sensor.

- 8 ECG key for first lead
- 9 Bed/patient ID
- 10 ECG waveform for first lead

## Printing SpO<sub>2</sub> Waveforms

This feature is not supported in telemetry products.



## SpO<sub>2</sub> Messages at the Host Monitor

### Caution:

Status messages indicate problems or conditions that may affect accurate monitoring values. Do not ignore these messages. Correct any fault before continuing.

When a status message appears, the saturation value and pulse rate immediately change to ???. An alarm may occur if your module is configured to do so. Depending on the configuration and option purchased, this alarm may not occur until after the message alarm delay time has elapsed.

Telemetry products use different text for  $SpO_2$  status messages than non-telemetry products. Telemetry products also show status messages within the ECG display zone, therefore, the ECG alarm messages that follow take priority over other  $SpO_2$  messages.

- LEADS OFF
- NOISY SIGNAL
- ECG ALARMS SUSPENDED

Refer to the customer documentation for your monitor for complete information on potential status messages which may appear at a host monitor that is configured with a 96281-A, 96281-B, 96281-C telemetry transmitter.

When a status message appears, the saturation value and pulse rate immediately change to ???. An alarm may occur if your module is configured to do so. Depending on the configuration and option purchased, this alarm may not occur until after the message alarm delay time has elapsed.

Telemetry products use different text for  ${\rm SpO_2}$  status messages than non-telemetry products. Refer to Table 3-5 for interpretations of the telemetry messages.

Telemetry products also show status messages within the ECG display zone, therefore, the ECG alarm messages that follow take priority over other SpO<sub>2</sub> messages.

- LEADS OFF
- NOISY SIGNAL
- ECG ALARMS SUSPENDED

Table 3-5 Telemetry Message Equivalents

Telemetry SpO <sub>2</sub> Message
SPO2 SENSOR DISCONNECTED
SPO2 FAULTY SENSOR
SPO2 SENSOR DISCONNECTED
SPO2 SENSOR OFF PATIENT
SPO2 INSUFFICIENT SIGNAL

### Table 3-5 Telemetry Message Equivalents (Continued)

Telemetry SpO <sub>2</sub> Message
SPO2 AMBIENT LIGHT INTF.
SPO2 NOISY SIGNAL
SPO2 INSUFFICIENT SIGNAL

### SENSOR DISCONNECTED — Check connection at adapter cable

This message and alarm indicate that the sensor is either disconnected or the wiring is faulty.

- Check for proper sensor connection to the adapter cable.
- If the message persists, replace the sensor and/or the adapter cable

### SENSOR OFF PATIENT — Check connection at patient

- The telemetry transmitter does not detect a valid sensor input signal. Check the patient for proper sensor placement.
- The tissue between the LED and photodiode is too transmissive. If the sensor placement seems correct and the message persists, try a sensor site with a thicker tissue bed.

### Note:

This message is not available with all SpO<sub>2</sub> sensors.

## INSUFFICIENT SIGNAL — Reposition or replace sensor

- Insufficient signal for proper operation, indicated by a low deflection on the Sensorwatch signal strength bar.
- · Poor sensor application or site. Correctly reapply or reposition to a better perfused site, or massage the site.
- If the message persists, then replace the sensor.

## LOW SIGNAL STRENGTH — Reposition or replace sensor

When this message appears, the saturation and pulse rate continue to show. However, the Sensorwatch bar flashes as an indication of a possible error condition.

- Insufficient blood flow between the sensor light emitter and detector. Move the sensor to an area of higher perfusion.
- Poor sensor application. Reposition to place active components closer to the skin or locate to a better perfused site.
- The sensor site is below the blood pressure cuff. Move to another site.
- If the message persists, then replace the sensor.





### AMBIENT LIGHT INTERFERENCE — Cover sensor area

- The sensor is receiving external light interference from a bright light source near the sensor. Shield the sensor from the external light source.
- The sensor photodiode and LED are misaligned on flexible sensors, allowing light to enter. Realign the sensor photodiode with the LED.
- If the message persists, then replace the sensor.

### **NOISY SIGNAL**

- The sensor signal is disturbed by motion or other interference. Eliminate sensor movement.
- Power cords or other electrically noisy devices are too close to the sensor. Move the noisy device or move the sensor to another site
- If the message persists, then replace the sensor.

### FAULTY SENSOR - Replace sensor

- The LED or photodiode (or both) may have failed.
- Ensure the sensor is properly connected, disconnect and then reconnect the sensor.
- If the error occurs again, replace the sensor and/or sensor adapter cable.
- If replacing the sensor and/or cable does not correct the problem, contact your Spacelabs Healthcare Field Service Engineer.

### HARDWARE INCOMPATIBILITY - Contact service

The hardware configuration in your module is not compatible with the programmed software options.

• Contact your Spacelabs Healthcare Field Service Engineer.

## Sensors

For SpO<sub>2</sub> sensor compatibility, refer to the information that follows.

## Spacelabs Healthcare SpO<sub>2</sub> Sensors

Please refer to the the accessories in *Telemetry Transmitter* (96281) *Data Sheet* for compatible sensors (for the 96281-C) and adapter cables.

### Additional Information

For additional information about biocompatibility or sensor disposal, refer to the manufacturer's instructions enclosed with each sensor.

## SpO<sub>2</sub> Alarm Delays

Table 3-6 SpO<sub>2</sub> Alarms

Alarm Setting	Range	Alarm Delay	
Spacelabs Healthcare			
Sat Low	50 to 99%	<ul> <li>Less than (15 seconds + user selected alarm delay)</li> <li>Alarm delay is user selected from 0 to 30 seconds in 5 second increments.</li> </ul>	
Sat High	51 to 100%	<ul> <li>Less than (20 seconds + user selected alarm delay)</li> <li>Alarm delay is user selected from 0 to 30 seconds in 5 second increments.</li> </ul>	

## SpO<sub>2</sub> Troubleshooting Guide

Clinical Situation	Possible Cause	Solution
No SpO <sub>2</sub> parameter key in Channel Format menu	• SpO <sub>2</sub> is not enabled at the 90478 receiver.	<ul> <li>Enable multiparameter telemetry in the Module Configuration Manager or enable the SpO<sub>2</sub> display in the <b>Channel Format</b> menu.</li> </ul>
SpO <sub>2</sub> value shows as ???	Sensor is not connected to the patient.	Reattach the sensor.
	There is excessive patient motion.	<ul> <li>Request patient to remain still while reading is in progress.</li> </ul>
	<ul> <li>Module is in the initialization phase (the first 15 seconds after sensor application).</li> </ul>	<ul> <li>Wait until the initialization is complete.</li> </ul>
	<ul> <li>Adapter cable is improperly connected to the telemetry transmitter.</li> </ul>	<ul> <li>Correctly connect the adapter cable.</li> </ul>
	<ul> <li>Sensor is not connected to the adapter cable.</li> </ul>	Correctly connect the sensor.
	<ul> <li>Telemetry low battery indicator is constantly illuminated.</li> </ul>	<ul> <li>Contact your biomed or a qualified field service engineer.</li> </ul>



Clinical Situation	Possible Cause	Solution
Low signal strength	Sensor placement is not	<ul> <li>Move the sensor to a site</li> </ul>
-OR- Insufficient Signal	optimum.	which has better perfusion.
		<ul> <li>Align the LED with the sensor photo detector.</li> </ul>
	<ul> <li>Sensor is placed below the blood pressure cuff.</li> </ul>	<ul> <li>Move the sensor to an alternate limb.</li> </ul>
Intermittent or complete failure to operate	Receiver or transmitter error.	<ul> <li>Contact your biomed or a qualified field service engineer.</li> </ul>
Factors causing significant variances in sensor accuracy	Presence of dysfunctional hemoglobins (COHb, MetHb).	<ul> <li>Follow hospital procedure for determining oxygenation in these patients.</li> </ul>
	<ul> <li>Presence of intravascular dyes (indocyamine green, methylene blue) in the blood stream.</li> </ul>	<ul> <li>Follow hospital procedure for determining oxygenation in these patients.</li> </ul>
	High ambient light level.	<ul> <li>Reduce light levels near the patient.</li> </ul>
	Electrosurgical interference.	<ul> <li>Follow hospital procedure for determining oxygenation in these patients.</li> </ul>
	<ul> <li>Patient is significantly anemic (Hb less than 5 g/dl) or has received large amounts of IV solutions.</li> </ul>	<ul> <li>Follow hospital procedure for determining oxygenation in these patients.</li> </ul>
No SpO <sub>2</sub> alarms are shown	ECG "Leads Off" condition exists.	<ul> <li>Re-attach ECG leadwires to the patient and resume ECG monitoring.</li> </ul>
	Higher priority alarm condition is present.	<ul> <li>Clear the current alarm condition and/or re-prioritize SpO<sub>2</sub> alarms in the Module Configuration Manager.</li> </ul>
		<ul> <li>When SpO<sub>2</sub> alarms are ON, all SpO<sub>2</sub> alarm conditions cause the parameter value to blink according to the alarm priority set using the Module Configuration Manager.</li> </ul>
FAULTY SENSOR Replace Sensor	A faulty or incompatible sensor is connected to the adapter cable.	<ul> <li>To clear the message, connect a known good sensor to the adapter cable.</li> </ul>
	Sensor has failed.	,





## **Basic Operations**

## **Getting Started**

Device setup must be performed before patient application and, on appropriate units, the LCD should be visually verified to function before use on a patient.

### Transmitter Batteries

When batteries are installed, the transmitter is continuously ON. If no batteries are installed, the transmitter is OFF. To extend battery life, insert batteries only to use the transmitter with a patient. Remove the batteries when the transmitter is not in use.

Spacelabs Healthcare recommends two AA 1.5-volt alkaline batteries for standard use in the digital telemetry transmitter for a battery source of 3 volts. Alternatively, you may use two AA-equivalent 2400 mAH NiMH rechargeable batteries.

Check the battery position and polarity, as shown at the bottom of the battery compartment on the device. After battery installation, close and latch the compartment cover. Transmission of telemetry signals begin as soon as the battery is in place.

Refer to Battery Compartment (96281-A, 96281-B, 96281-C) on page 4-8 for details on battery compartment labels and components.

### Warnings:

- Batteries exposed to short circuit, high temperature, or fire may leak, vent, or explode.
- Do not use any transmitter that has been compromised by liquid ingress.



- Users should inspect batteries before using them within the transmitter—do not use any batteries that appear to be damaged or have been subject to misuse.
- Do not use any transmitter that has been compromised by liquid ingress. If fluid has collected in the battery compartment, clean and dry it before use. If the transmitter has been immersed in liquid, it must be thoroughly dried before use. Not doing so may prevent the transmitter from working properly. If the SpO<sub>2</sub> sensor has been immersed in liquid, it should be dried and inspected for proper operation and replaced if necessary.
- Do not attempt to use depleted batteries or mix different types of batteries. Doing so may result in the telemetry transmitter being unable to accurately determine the battery condition and prevent the transmitter from working properly. If the battery low indicator flashes as soon as batteries are inserted, then they are too depleted to be used and the transmitter will not work properly. Replace with new or fully-charged batteries immediately.

### Cautions:

- Obey the battery manufacturer's recommended handling procedure.
- Collect and transport batteries in a manner that prevents short circuit, compacting, mutilation, or any other abuse that would compromise the physical integrity.
- Clean the transmitter case with the battery door closed. If fluid or other contaminants have collected in the battery compartment, clean and dry it before use.
- Inspect and check the transmitter for damage prior to every procedure.
- Use either new alkaline batteries or fully-charged 2400 mAH NiMH rechargeable batteries for each and every new procedure.
- Clean the transmitter after each use. Refer to the *Telemetry* Transmitter (96281-A, 96281-B, 96281-C) Service Manual (P/ N 070-2408-xx), located on the *Telemetry Service* (9628X) CD (P/N 084-2202-xx) for preventive maintenance instructions.
- Make sure that service on the transmitter is performed by authorized Spacelabs Healthcare service personnel when repairs are necessary or at suitable intervals.

### Notes:

The description that follows of transmitter operation is valid only for two AA 1.5-volt alkaline or two AA-equivalent 2400 mAH NiMH rechargeable batteries and does not apply to any other type of battery.

When a low battery condition is detected, the orange battery status indicator illuminates on the front cover of all three transmitter models: 96281-A, 96281-B, 96281-C. In addition, a



red battery symbol appears in the display of the 96281-B and 96281-C transmitters.

- Used batteries must be properly disposed of or recycled according to national and/or local regulation.
- Refer to the product service manual for more details.

### **Host Monitors**

The 96281 telemetry transmitter is compatible with the Ultraview SL 3800-38/-39 central monitor and the Ultraview and Ultraview SL line of bedside monitors. For information on configuring battery alarm status, enabling and adjusting alarms, assigning telemetry channels, status or interference messages, refer to the operations and service manuals for the specific monitor in use with the telemetry transmitter devices.

If you use Ultraview SL 3800-38 or 3800-39 central monitor,

 refer to the *Ultraview SL Operations Manual* (P/N 070-1150-xx), 91387 Service Manual (P/N 070-1159-xx), and to the *Clinical Parameters Operations Manual* (P/N 070-2113-xx) for more information.

## Telemetry Receiver Module

The telemetry transmitters are compatible with the 90478 Digital Telemetry System Receiver and Receiver Housing (90479-A, 90479-B, 90479-C). The receiver housing is related to the central monitor. The receiver module can go in the housing or in a bedside monitor.

Refer to Clinical Parameters Operations Manual (P/N 070-2113-xx) located on the Patient Monitoring Operations Documents CD (P/N 084-1101-xx) and to the Spacelabs Healthcare Service CD (P/N 070-0700-xx) for detailed information relating to the 90478 and 90479 digital telemetry systems.

### Warning:

All system connections (except for those related to moving receivers from one monitor or housing to another) must be made by trained or qualified personnel only. Changes or modifications not expressly approved by Spacelabs Healthcare may void the user's authority to operate the equipment.

### Cautions:

- Telemetry transmitters have preassigned channel numbers (frequencies) that cannot be changed. The channel number is identified on the back cover of the transmitter.
- Only qualified personnel should tune telemetry receiver modules to receive data from a telemetry transmitter.
   Telemetry receiver modules must be used with a transmitter on the same frequency.

· Qualified service personnel should set the telemetry receiver's frequency band via the Module Configuration Manager feature.

## Assigning a Telemetry Channel

When connecting a new patient to a transmitter, make sure the prior patient's information has been purged at the host monitor.

Your central station can only show a telemetry channel after that channel has been assigned a specific bed or room number. Refer to the user manuals for your central monitor or station for information to assign a specific bed name to a telemetry channel and to assign the bed to a specific display zone. Your central monitor can be configured to remember the bed name assigned to individual telemetry channels. These beds are permanently assigned until you unassign or reassign them. Refer to the Ultraview SL Module Configuration Manager System Administration Guide (P/N 070-1245-xx) for more information.

## **Basic Components**

The 96281-B telemetry transmitter is essentially the same as the 96281-C model, except for the SpO<sub>2</sub> capability. Thus the components described in the illustrations of the 96281-C are also applicable to the 96281-B model except for the SpO<sub>2</sub> connector cap.

The 96281-A model is similar to the 96281-B and 96281-C but it does not include a display or an SpO<sub>2</sub> connector cap or functionality (refer to Figure 4-3 on page 4-7).



## Top, Front and Bottom View (96281-C)

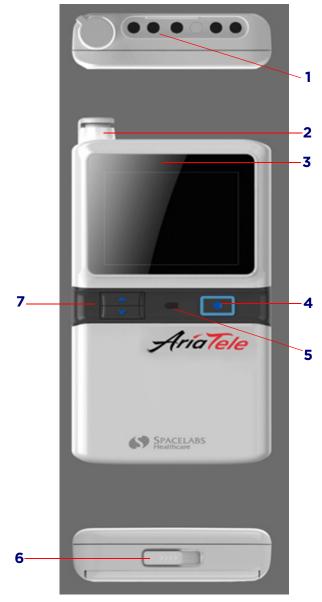


Figure 4-1 Top, front, and bottom views (96281-C)

- 1 Top view showing lead inputs and SPO<sub>2</sub> connector cap  $(SPO_2 \text{ cap on } 96281\text{-C only})$
- 2 Front view of SPO<sub>2</sub> connector cap (96281-C only)
- 3 Location on display where lead fault indicators show (96281-B, 96281-C)
- 4 Action button

### Note:

The nurse may instruct the patient to press the **Action** button if he or she experiences any discomfort.

**5** Low battery indicator

- 6 Bottom view of the battery compartment latch
- 7 Up/down buttons for LCD configuration (96281-B and 96281-C only)

## Rear View (96281-C)

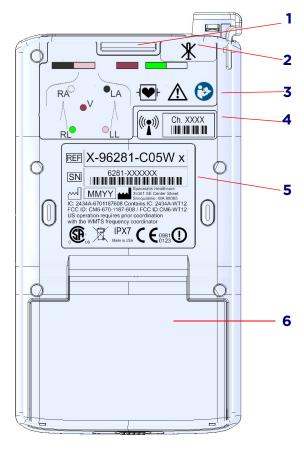


Figure 4-2 Rear view (96281-C)

- 1 Grouper (includes a clip)
- 2 "Do not modify" symbol (repairs and modifications must be done by Spacelabs Healthcare authorized personnel)
- 3 ECG label (includes lead legend and leads placement diagram)
- 4 Channel identifier
- 5 Manufacturing technical label
- 6 Battery compartment cover



## Front View (96281-A)



Figure 4-3 96281-A Telemetry Transmitter

- 1 Lead fault indicators on 96281-A (up to five triangular shapes may illuminate when activated by a lead off condition)
- 2 Action button
- **3** Low battery indicator

## Battery Compartment (96281-A, 96281-B, 96281-C)

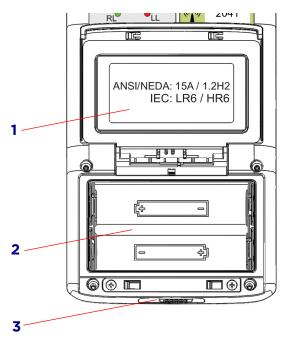


Figure 4-4 Details of battery compartment (cover open)

- 1 Battery type label affixed to underside of open battery compartment cover
- 2 Battery polarity label
- **3** Battery compartment latch (on bottomside)



## Selecting Options for Leads

Up to five standard, disposable, silver/silver chloride chest electrodes are connected to the patient. The ECG leadwires are attached to these electrodes and connected to the transmitter.

Refer to Figure 4-5 on page 4-9 for leads placement and  ${\rm SpO}_2$  connections.

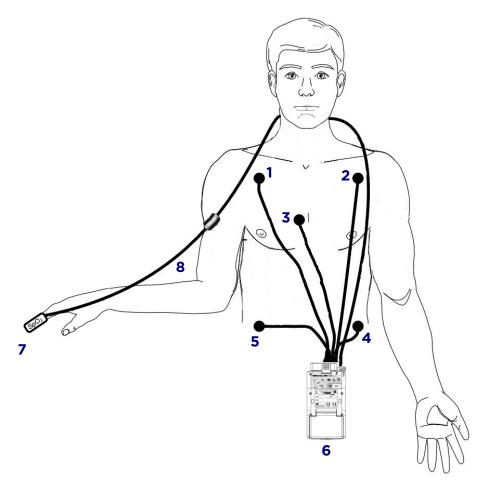


Figure 4-5 ECG leads placement and SpO2 connections

- **1** RA
- **2** LA
- **3** \
- **4** LL
- **5** RL
- 6 96281-C telemetry transmitter
- 7 SpO<sub>2</sub> sensor
- 8 SpO<sub>2</sub> cable

Monitors and transmitters may be placed in pouches and attached to the patient's belt.

### Notes:

- If one of the leads fails, a lead fault message shows on the host monitor.
- If there is no valid lead vector, the message CHAN 1 & 2 -LEADS OFF shows and an alarm tone sounds only at the host monitor.

## **Basic User Actions**

The up and down arrow buttons (refer to 7 in Figure 4-1 on page 4-5) provide navigational control, such as moving through ECG and SpO<sub>2</sub> displays. These up/down buttons are only included on the 96281-B and 96281-C models.

All 96281 devices include the Action button (refer to item 4 in Figure 4-1 on page 4-5). If a patient or user presses this button, and keeps the button pressed for approximately one and a half seconds, the transmitter sends an "event" to the host monitor. The transmitter provides visual indication of such "events" by flashing all its LEAD OFF indicators on-off, on-off, twice in quick succession. The corresponding action at the host monitor, depends on the configuration settings of the host monitor, so please refer to the Monitor Operations Manual, but typically events are used to generate strip recordings.

### Warnings:

- Do not use any transmitter that has been compromised by liquid ingress.
- Do not use any transmitter that has been compromised by liquid ingress. If fluid has collected in the battery compartment, clean and dry it before use. If the transmitter has been immersed in liquid, it must be thoroughly dried before use. Not doing so may prevent the transmitter from working properly. If the SpO<sub>2</sub> sensor has been immersed in liquid, it should be dried and inspected for proper operation and replaced if necessary.
- Readings for SpO<sub>2</sub> should not be taken from the same arm that has an NIBP cuff attached.

### Caution:

Clean the transmitter after every procedure (refer to Cleaning, Disinfecting, and Sterilization on page 5-1 for more information).

### Notes:

· Should all of the lead fault indicators illuminate and stay illuminated during operation, then the AriaTele transmitter has detected an internal fault condition. If this occurs, the device will stop transmitting and will not show any ECG or SpO2 information. To clear this condition, install new batteries.



• If all of the lead fault indicators remain permanently illuminated, please contact your Spacelabs Healthcare service representative for assistance.

## To send a recording to the central monitor or station

• From either the view or non-view mode, firmly push the action button for 2 seconds. Refer to Basic Modes of Operation on page 4-11 for more information.

### Note:

The record function must be enabled at the central station to send a recording. Refer to the operations manual for your central station for more information.

## To unlock the user interface on the 96281 telemetry transmitter

• Push and hold the up and down buttons simultaneously for at least three seconds.

### Note:

When the user interface is locked, the LCD appears blank, even though the transmitter is in a non-view mode and still transmitting.

## Basic Modes of Operation

There are three basic operating modes to the telemetry transmitter.

- 1 Off
- 2 View
- 3 Non-View

Table 4-1 Basic Modes of Operation

Operating Mode	Description	
Off	The device is off and is not in use if there are no batteries installed.	
View	96281-B, 96281-C	
	<ol> <li>User can view patient vital signs on the host monitor or transmitter LCD.</li> </ol>	
	2 User can initiate printing.	
	<b>3</b> Patient vital signs are transmitted to the central station.	
	After 60 seconds of inactivity, the unit moves to the non-view mode.	

Table 4-1 Basic Modes of Operation (Continued)

Operating Mode	Description	
Non-View	96281-A, 96281-B, 96281-C	
	Note: Since the 96281-A does not have an LCD, it is either continuously in non-view mode or is OFF.	
	<b>1</b> The LCD is off on the 96281-B or 96281-C.	
	2 User can initiate printing.	
	<b>3</b> Patient vital signs are transmitted to the central station.	
	<b>4</b> User can return to the view mode by unlocking the user interface (96281-B or 96281-C only).	
	To unlock the interface, push and hold the up and down buttons simultaneously for at least three seconds.	

### Note:

The 96281-C automatically detects a sensor connection and activates or deactivates the  $SpO_2$  option accordingly.

## View Mode

View Mode is available only with transmitters that include a display (96281-B or 96281-C), so it is not applicable to the 96281-A telemetry transmitter.

### **ECG**

ECG data is obtained directly from the patient connection and shows on the transmitter LCD as shown in Figure 4-6, depending on configuration of leads and available parameters.



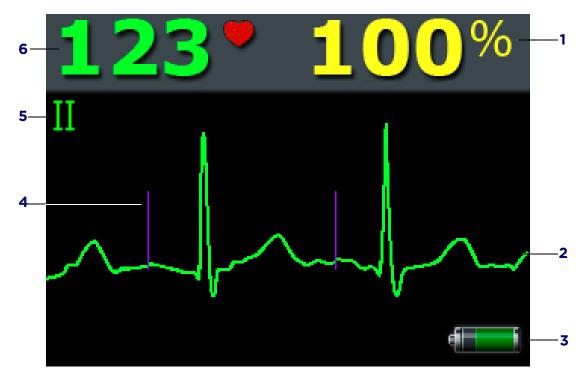


Figure 4-6 Paced ECG and SpO<sub>2</sub> display on the 96281-C

- 1 SpO<sub>2</sub> saturation percentage (available on 96281-C only)
- 2 ECG waveform
- **3** Battery charge indicator (shows the battery state)
- 4 Pacing marker
- 5 Shown lead indicator
- **6** Heart rate derived from ECG (indicated by solid heart icon)

### Notes:

The AriaTele acquires and transmits ECG data in samples. In addition, it may show the ECG waveform on its optional display. When the AriaTele acquires an ECG sample that it detects as possessing a pacing pulse, it does two things:

- It sends a notification to the receiving system, indicating that the ECG sample contained a pacing pulse.
- It marks the location of the pacing pulse, on its optional display, using purple pacing markers as shown.

The receiver system uses the information it receives to mark corresponding purple pacing pulses on the ECG waveform that it receives.

### Notes:

- ECG leads show in the order that follows: Lead II, V, Lead I, Lead III.
- If a lead is not available due to electrode configuration, that lead shows as a straight line on the display.

• Pacing marker (shows only if detected) is shown as a vertical purple line.

The symbols that follow show on the 96281-B and 96281-C telemetry transmitter LCD when numerics are not available or are out of the designated range for a parameter.

Not available	???
Under range	
Over range	+++

## SpO<sub>2</sub>

SpO<sub>2</sub> is only available with the 96281-C. SpO<sub>2</sub> data is obtained directly from the patient and may show as in Figure 4-7, depending on configuration of leads and available parameters.

The 96281-C auto-detects a sensor connection and activates or deactivates the SpO<sub>2</sub> option accordingly.

### Note:

SpO<sub>2</sub> view does not show if a SpO<sub>2</sub> adapter cable is not connected.



Figure 4-7 Typical SpO<sub>2</sub> display on 96281-C (shows a low battery state)

- 1 SpO<sub>2</sub> saturation percentage (96281-C only)
- 2  $SpO_2$  pulse waveform (96281-C only)
- **3** Battery charge indicator (defined by quartiles)
- 4 Signal quality/strength indicator (at least one color bar in the indicator is recommended for a reliable SpO<sub>2</sub> value)
- **5** Pulse rate derived from SpO2 (indicated by an asterisk)



## Status Messages at the Host Monitor

Various status messages related to the telemetry transmitter may show at the host monitor when there is a problem with the signal or when the battery is low. The host monitor may be either the central station or bedside monitor.

### Caution:

- Do not ignore status messages.
- SpO<sub>2</sub> data may not show when the INTERMITTENT SIGNAL LOSS message appears.
- Status messages indicate a problem or condition which may affect accurate monitoring values.
- Correct any fault before continuing.

The status messages that follow may appear at the host monitor. Refer to SpO2 Messages at the Host Monitor on page 3-17, for status messages related to  ${\rm SpO}_2$ .

INTERMITTENT SIGNAL LOSS

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. A low-priority alarm occurs after 10 seconds in this condition.

LOW BATTERY

Indicates the battery is weak. After this message appears, the battery has approximately one hour of useful life left (depending on the type of battery used). Install a new battery. A low-priority alarm occurs if the setup menu's LOW BAT ON/OFF key is set to ON.

SIGNAL INTERFERENCE

Indicates, through the triangle-shaped squelch waveform, that an interfering signal has been detected. The patient's signal can no longer be detected because of interference from a stronger signal source lasting more than 0.5 seconds. A low priority alarm occurs whenever this message appears in the waveform zone.

IS SIGNAL LOSS PERMANENT?

Indicates no radio frequency (RF) signal is detected.

## Telemetry Transmitter with ECG Only Troubleshooting Guide

Clinical Situation	Possible Cause	Solution
Low battery LED flashing	The batteries are low.	Replace batteries.

Clinical Situation	Possible Cause	Solution
All leads off LEDs lit	Self test failure.	Contact Spacelabs     Healthcare.
Any or all leads off LEDs flashing	Check ECG leads.	
ECG is not shown at Central Station	Check if batteries are low.	Replace batteries.
ECG is not shown at Central Station	Unit malfunction.	<ul> <li>Contact Spacelabs Healthcare.</li> </ul>

## Telemetry Transmitter with Display Troubleshooting Guide

Clinical Situation	Possible Cause	Solution
Low battery LED flashing	The batteries are low.	Replace batteries.
All leads off LEDs lit	Self test failure.	Contact Spacelabs     Healthcare.
Any or all leads off LEDs flashing	Check ECG leads.	
ECG is not shown at Central Station	Check if batteries are low.	Replace batteries.
ECG is not shown on transmitter display	Unit malfunction.	Contact Spacelabs     Healthcare.

## Telemetry Transmitter with Display and SpO<sub>2</sub> Troubleshooting Guide

Clinical Situation	Possible Cause	Solution
Low battery LED flashing	The batteries are low.	Replace batteries.





Clinical Situation	Possible Cause	Solution
All leads off LEDs lit	Self test failure.	Contact Spacelabs     Healthcare.
Any or all leads off LEDs flashing	Check ECG leads.	
ECG is not shown at Central Station	Check if batteries are low.	Replace batteries.
SpO <sub>2</sub> data is not shown on transmitter	<ul> <li>SpO<sub>2</sub> cable and/or sensor is faulty.</li> </ul>	<ul> <li>Check SpO<sub>2</sub> cable and sensor.</li> </ul>
display	• Unit malfunction.	<ul> <li>Contact Spacelabs Healthcare.</li> </ul>
SpO <sub>2</sub> is not shown at Central Station	Unit malfunction.	Contact Spacelabs     Healthcare.





# Cleaning, Disinfecting, and Sterilization

## Cleaning Products Not Recommended for Use

### Warnings:

- Do not use Accelerated Hydrogen Peroxide (AHP) and quaternary ammonia-based products to clean the transmitter, leadwires, cables, or sensors. Common quaternary ammonia germicidal products include Cavicide, Virex, Virex 256, SaniCloth, and Sanicloth Plus.
- These chemicals attack the plastics used in patient monitors and cables, and will cause serious safety hazards as the electrical insulating properties and structural integrity of the equipment break down.
- These germicidal products are safe for use ONLY on hard, non-porous surfaces, such as linoleum floors, formica countertops, and stainless steel.

## Cleaning the Display

Clean the display with a soft cloth moistened with either 70% isopropyl alcohol solution or soapy water.

### Notes

Obey your hospital protocol for the handling of blood and body fluids.

## Transmitter, Leadwires, Cables, and Sensors

## Cleaning/Disinfecting

### Warnings:

- · Use only recommended cleaning solutions, or you may void the manufacturer's warranty.
- Harsh chemical agents degrade plastics and compromise the safety of the device. Some germicidal and other harsh cleaning compounds are known to damage some plastics by weakening the structural integrity and compromising the electrical insulating properties.
- Disconnect the equipment from the patient before cleaning.
- Do not immerse the equipment or cables in water or cleaning solutions.
- Do not autoclave.

## Recommended Cleaning Solutions

Use only the recommended cleaning solutions that follow:

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

### Caution:

Questions and concerns about cleaning issues should be directed to Spacelabs Healthcare Technical Support.

### Note:

- Repeated use of a chlorine bleach solution may cause some colors to fade.
- Tape adhesive can be removed with Spacelabs Healthcare adhesive tape remover pads (P/N 392196-001).

### Accessories

- Where provided, obey the manufacturers' instructions concerning disposable and reusable supplies.
- As applicable, obey your hospital protocol concerning cleaning, disinfection, and/or sterilization of reusable supplies.
- Obey hospital protocols to dispose of used and contaminated single-use accessories.



## Cleaning and Disinfecting the 96281Telemetry Transmitters and Cables

In normal use the product is worn by one hospital patient for a few days. Clean and disinfect the transmitter after every procedure and/or before it is worn by another patient. There is a risk that the product may carry dangerous levels of infectious agents to the next patient if it is not adequately cleaned and/or disinfected.

Refer to Recommended Cleaning Solutions on page 5-2 for a list of acceptable cleaning solutions.

## Basic Cleaning and Low-level Disinfection

- 1 Remove the batteries and close the battery cover.
- 2 Remove the ECG leadwires, grouper, and SPO<sub>2</sub> cable (if fitted).
- **3** Inspect the transmitter for contamination. If required and carry out steps 4 and 5 to clean the transmitter.
- **4** Rub the transmitter with a cloth wetted in a mild detergent solution.
- 5 Dry the transmitter thoroughly.
- 6 Prepare the cleaning solution chosen from the list of recommended cleaning solutions according to the manufacturer's instructions.
- 7 Wet a clean cloth with the selected cleaning solution.
- **8** Remove excess liquid from the cloth and squeeze dry.
- **9** Wipe all exposed surfaces of the equipment and cables.
- 10 Leave the transmitter for the required contact time, during which it should remain wet.
- 11 Remove any soap residue by gently wiping with a clean damp cloth.
- 12 Wipe dry with a clean dry cloth.
- **13** Take steps to remove disinfectant residues in accordance with the disinfectant labelling.

## Cleaning ECG Leadwires

Inspect the leadwire sockets for contamination. If necessary, flush using a syringe and clean using a toothpick. Once clean, Spacelabs Healthcare recommends wetting the sockets with 70% isopropyl alcohol to provide low level disinfection. This agent can be left to dry naturally and does not require any rinse procedures.

### Note:

After cleaning ECG leadwires, remove the ECG leadwires from the lead block and thoroughly dry them at the lead block ends and at the lead connector ends. Thorough drying will prevent residual moisture from providing a low-current path between leads, which can interfere with lead off detection and cause false asystoles.

## Cleaning Buttons

Clean the buttons by wetting a small brush with a mild detergent solution and gently scrubbing around and across the buttons. Dry the buttons with a rubbing action.

Disinfect the buttons by using the same method. Spacelabs Healthcare recommends using 70% isopropyl alcohol which can be left to dry naturally and does not require any rinse procedures.

## Cleaning the Battery Cover

Clean around the battery cover release with a small brush using a mild detergent solution. Disinfect using the same method with 70% isopropyl alcohol to provide low level disinfection.

Open the battery cover and inspect the hinges and catch for contamination. If necessary, flush using a syringe and clean using a small brush, taking care not to deform the cover spring. Once clean, we recommend wetting with 70% isopropyl alcohol to provide low level disinfection. This agent can be left to dry naturally and does not require any rinse procedures.





# Appendix A — Guidance and Manufacturer's Declaration

## Electromagnetic Environment

The 96281 telemetry transmitter is intended for use in the electromagnetic environment specified in the reference tables in this chapter. The customer or user of the 96281 should make sure that it is used in such an environment.

## Electromagnetic Emmissions

Table A-1 Electromagnetic Emmissions

Emission Test	Compliance	Electromagnetic Environment
RF emissions CISPR 11	Group 1	The 96281 emits electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The 96281 is suitable for use in all establishments, including those directly connected to the public low-voltage power supply network that supplies public buildings.
Harmonic emissions IEC 61000-3-2	N/A	N/A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	N/A

## **Electromagnetic Immunity**

Table A-2 Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	N/A	N/A
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	N/A	N/A
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	$ <5\% \ U_T $ (>95% dip in $U_T$ for 0.5 cycle) $ 40\% \ U_T $ (60% dip in $U_T$ for 5 cycles) $ 70\% \ U_T $ (30% dip in $U_T$ for 25 cycles) $ <5\% \ U_T $ (>95% dip in $U_T$ for 5 seconds)	N/A	N/A
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a commercial or hospital environment.

 $U_T$  is the AC mains voltage prior to application of the test level.

Conducted RF IEC 61000-4-6	N/A	N/A	Portable and mobile RF communications
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	equipment should be used no closer to any part of the monitoring device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.



### Table A-2 Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
			Recommended separation distance:
			d = 1.17 \[ \begin{align*} P \\ \ P \\ \ \ \ \ \ \ \ \ \ \ \ \ \
			80 MHz to 800 MHz
			d = 2.34 \ P
			800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W), according to the transmitter manufacturer, and d is the recommended separation distance in meters (m).
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than the compliance level in each frequency range.
			Interference may occur in the (((•))) vicinity of equipment marked with the following symbol.

<sup>\*</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the monitoring device are used exceeds the applicable RF compliance level above, the 96281 telemetry device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the 96281 telemetry device.

### Notes:

- At 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

## Separation Distances

The 96281 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the 96281 telemetry transmitter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 96281 as recommended below, according to the maximum output power of the communications equipment.

Table A-3 Separation Distances

Recommended separation distances between portable and

Rated maximum output

Separation distance according to

80 MHz to 800 MI d = $1.17 \sqrt{P}$	800 MHz to 2.5 GH d = $2.34 \sqrt{P}$
0.117	0.234
0.37	0.738
1.17	2.34
3.69	7.37
11.7	23.4
	d = 1.17 \bigcap P \\ 0.117 \\ 0.37 \\ 1.17 \\ 3.69

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

### Notes:

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.



## Appendix B — Symbols

The following list of international and safety symbols describes all symbols used on Spacelabs Healthcare products. No one product contains every symbol.

## Note:

Graphic elements of certain keys and symbols may vary between product lines.

RELP	HELP Key
?	HELP (Explain Prior Screen) Key
HOLLIGE	MONITOR SETUP Key
	REMOTE Key
Trends	TRENDS Key



RECORD .	RECORD Key
	Dynamic Network Access (DNA) Key
SPECIOLS	SPECIAL FUNCTIONS Key
NORTHIN SCREEN	NORMAL SCREEN Key
Save	SAVE Key
<del></del>	No Network Connection
<u>早</u> 日	Network Connection
	Do Not Connect to Network
- <mark>2</mark> -7-	No Connection to Intesys® Clinical Suite (ICS)
	Compression
	Magnifying Glass
	File Cabinet
2	List of Rooms
	Printer
	Service Message



PREVIOUS	PREVIOUS MENU Key
	HOME Key
	Arrows
<u> </u>	On Direction
I	ON — Power Connection to Mains
$\odot$	ON — Part of the Instrument Only
<u> </u>	ON Position for Push Button Power Switch
0	OFF — Power Disconnection from Mains
	OFF Position for Push Button Power Switch
Ċ	OFF — Part of the Instrument Only
$\dot{\odot}$	Partial ON/OFF
$\bigcirc$	ON/OFF
Ö	Standby
(J)	STANDBY Key Power ON/OFF Key
	Keyboard Connection



	Mouse Connection
$\bigcirc$	PAUSE or INTERRUPT
$\bigoplus$	START/STOP Key
\$∕⊗	START/STOP
$\bigcirc$	STOP or CANCEL Key
Ø	CONTINUE Key
<b>—</b>	ENTER Key
х	Delete
$\Leftrightarrow$	Nurse Alert Interface
$\triangle$	ALARM SUSPEND/TONE RESET Key
TONE	ALARMS Key
	Alarm, General
	Alarm Reset
$\triangle$	Alarm Audio ON
☆ ☆	Alarm Audio OFF
	Alarm Audio Paused



	Low Priority Alarm
	Medium Priority Alarm
	High Priority Alarm
	Alarms Paused
	Alarm OFF
	Parameter below measurement range
+++	Parameter above measurement range
???	Parameter measurement indeterminate
	Indicator — Remote Control
	PRINT REPORT Key
	Normal Screen
	Clock/Time Setting Key
	Slow Run
\$	Activate Recorder for Graphics
$\triangleright \triangleleft$	Reset



$\Diamond$	START (NIBP) Key
	Power Indicator LED
•	Activate Telemetry Recorder
<b>→</b>	Output (Non-terminated)
$\Leftrightarrow$	Data Input/Output
<b>→</b>	Input
<b>&gt;</b>	No Output (Terminated)
	Indicator — Local Control
$\boxtimes$	Indicator — Out of Paper
<b> </b>	Recorder Paper
	Menu Keys
	Waveform/Parameter Keys
1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Return to Prior Menu
1 2 3	Monitor Setup Select Program Options
1 A	Set Initial Conditions Menu



1 B	Access Special Function Menu
1 2 3	Return Unit to Monitor Mode
0 0 0 0 0 0 0 0 0	Keypad
1	Serial Port 1
<b>←</b> 2	Serial Port 2
$\Longrightarrow$	Serial Port
@	Auto Mode (NIBP)
•>	External Marker Push Button Connection
	Arterial Pulse
$\uparrow$	Gas Exhaust
	Video Output
	Television; Video Display
	Video Output, Primary
2	Video Output, Secondary
	Enlarge, Zoom



<del></del>	Input/Output
	PCMCIA Card
	Touchscreen, External
•	Universal Serial Bus
<b>★</b> SDLC	SDLC Port
	Hard Drive
Y	Antenna
$\Lambda$	Electrocardiograph or Defibrillator Synchronization
	Microphone
>	Foot Switch
	Audio Output, Speaker
\$	Event
	Gas Sampling Port
	Gas Return Port
	Battery Replace only with the appropriate battery.



	Battery Status
+ -	Battery Replace only with the appropriate battery.
	Low Battery
<u> </u>	Replace only with the appropriate battery. (+ / - signs may be reversed)
	All batteries should be disposed of properly to protect the environment. Lithium batteries should be fully discharged before disposal. Batteries such as lead-acid (Pb) and nickel-cadmium (Ni-Cd) must be recycled. Please follow your internal procedures and or local (provincial) laws regarding disposal or recycling.
X	This symbol indicates that the waste of electrical and electronic equipment <i>must not</i> be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.
A	Caution - hazardous voltages. To reduce risk of electric shock, do not remove the cover or back. Refer servicing to a qualified field service engineer (U.S.A.). DANGER - High Voltage (International)
	Protective Earth Ground
	Replace Fuse Only as Marked
⊝-€-⊕	Power supply jack polarity. (+ / - signs may be reversed)
~	Alternating Current
~	Both Direct and Alternating Current
<u></u>	Functional Earth Ground
<del></del>	Fuse
$\bigvee$	Equipotentiality Terminal



===	Direct Current
→ P/N 119-0527-XX	Input Power. Use only Spacelabs Power Supply (P/N 119-0527-xx).
	AC/DC Input
· 🔯 ·	Loop Filter
1	Audio Output, Speaker
<b>†</b>	IEC 60601-1 Type B equipment. The unit displaying this symbol contains an adequate degree of protection against electric shock.
4 <b>*</b>	IEC 60601-1 Type BF equipment which is defibrillator-proof. The unit displaying this symbol is an F-type isolated (floating) patient-applied part which contains an adequate degree of protection against electric shock, and is defibrillator-proof.
<b>†</b>	IEC 60601-1 Type BF equipment. The unit displaying this symbol is an F-type isolated (floating) patient-applied part providing an adequate degree of protection against electric shock.
4 <b>\\</b>	IEC 60601-1 Type CF equipment. The unit displaying this symbol is an F-type isolated (floating) patient-applied part providing a high degree of protection against electric shock, and is defibrillator-proof.
•	IEC 60601-1 Type CF equipment. The unit displaying this symbol is an F-type isolated (floating) patient-applied part providing a high degree of protection against electric shock.
	IEC 60601-1 Class II equipment, double-isolated. The unit displaying this symbol does not require a grounded outlet.
$\mathbb{X}$	Warning: Do not modify this equipment without authorization of the manufacturer.
!	Operates on Non-Harmonized Radio Frequencies in Europe
Ť	Adult Noninvasive Blood Pressure (NIBP)
	Fetal Monitor Connection (Analog)



(A)	Fetal Monitor Connection RS-232 (Digital)
√	Physiological Monitor Connection RS-232 (Digital)
	Noninvasive Blood Pressure (NIBP),
	Symbol Set, Adult/Pediatric Cuff Sizes
o⊪ o⊪s o⊪s	Symbol Set, Neonatal Cuff Sizes
Q#s	NIBP Cuff, Neonatal 1
Q#s	NIBP Cuff, Neonatal 2
Q# <i>&gt;</i> >	NIBP Cuff, Neonatal 3
Q#~	NIBP Cuff, Neonatal 4
Q#A	NIBP Cuff, Neonatal 5
<b>©</b> 7	NIBP Cuff, Single Hose
	NIBP Cuff, Dual Hose
THIS SIDE TO PATIENT	NIBP Cuff, Surface Applied to Patient
CHILD	NIBP Cuff, Child Size (12 to 19 cm)



CHILD, LONG	NIBP Cuff, Child Size, Long (12 to 19 cm)
SMALL ADULT, LONG	NIBP Cuff, Small Adult Size, Long (17 to 25 cm)
SMALL ADULT	NIBP Cuff, Small Adult Size (17 to 25 cm)
ADULT, LONG	NIBP Cuff, Adult Size, Long (23 to 33 cm)
LARGE ADULT, LONG	NIBP Cuff, Large Adult Size, Long (31 to 40 cm)
LARGE ADULT	NIBP Cuff, Large Adult Size (31 to 40 cm)
ADULT	NIBP Cuff, Adult Size (23 to 33 cm)
INFANT	NIBP Cuff, Infant Size (8 to 13 cm)
NEONATAL 1	NIBP Cuff, Neonatal 1 Size (3 to 6 cm)
NEONATAL 2	NIBP Cuff, Neonatal 2 Size (4 to 8 cm)
NEONATAL 3	NIBP Cuff, Neonatal 3 Size (6 to 11 cm)
NEONATAL 4	NIBP Cuff, Neonatal 4 Size (7 to 13 cm)
NEONATAL 5	NIBP Cuff, Neonatal 5 Size (8 to 15 cm)
THIGH	NIBP Cuff, Thigh Size (38-50 cm)
NYLON	NIBP Cuff, Nylon Material



SOFT	NIBP Cuff, Soft Material
VINYL	NIBP Cuff, Vinyl Material
QTY	Quantity
ARTERY	Place Artery Symbol and Arrow over Brachial or Femoral Artery
SKN indicate	eIFU = electronic Instructions for Use (CD-ROM or website) is available
Ti (**)	Follow Instructions For Use
Warning	Warning About Potential Danger to Human Beings (Consult Accompanying Documents)
Caution	Caution About Potential Danger to a Device (Consult Accompanying Documents)
Note	Note
	Keep Dry
	Indoor Use Only
12,200 m	Environmental Shipping/Storage Altitude Limitations
470	Environmental Shipping/Storage Temperature Limitations



	Fragile; Handle with Care
111	This Way Up
$\triangle$	Up Arrow
$\downarrow$	Down Arrow
95%	Environmental Shipping/Storage Humidity Limitations
	Open Padlock
	Closed Padlock
$\odot$	Happy Face
	Sad Face
PVC	PVC-Free (Polyvinyl Chloride)
2	Do Not Reuse; Single Use Only
	Reusable
IPX1	Drip-Proof
IPX7	Unit can withstand accidental immersion in one meter of water for up to 30 minutes
REF	Reference Number or Order Number



	Use by date [YYYY-MM-DD]
	Recycle
NON	Non Sterile
LATEX	Latex-Free
	Date of Manufacture
	Manufacturer
$(((\bullet)))$	Radio transmitting device; elevated levels of non-ionizing radiation
CE	A CE mark certifies that a product has met EU health, safety, and environmental requirements, which ensure consumer safety.
CExxxx	XXXX is the European Notified Body number. 0123 is the number for TÜV SÜD Product Service GmbH, München, Germany.
®	Canadian Standards Association Approved
LOT	Batch Code
NE 2	Nellcor Oxisensor II Compatible
NV X	Novametrix Compatible
Tru <mark>Li</mark> nk°	Spacelabs TruLink Compatible



OXIMAX	Nellcor OxiMax Compatible
67	Spacelabs Compatible
c <b>FL</b> °us	UL recognized component in Canada and United States
OXIMAX WORKS &	Nellcor OxiMax Compatible
<b>♥</b> Masimo SET	Masimo SET Compatible

## ABBREVIATIONS USED AS SYMBOLS ARE SHOWN BELOW.

1 - 32	Access Codes 1 Through 32
AIR	Air
Α	Amperes
ANT 1 ANT 2	Diversity Antenna System 1 Diversity Antenna System 2
Arr1 ArrNet2	Arrhythmia Net 1 Arrhythmia Net 2
avDO <sub>2</sub>	Arterial/Venous Oxygen Difference
CaO <sub>2</sub>	Arterial Oxygen
CH ch	EEG, EMG, or ECG Channel EEG Channels - CH1, CH2, CH3, CH4 EMG Channel - CH5
cmH <sub>2</sub> O	Centimeters of Water
C.O. CO	Cardiac Output
CvO <sub>2</sub>	Venous Oxygen
CO2 CO <sub>2</sub>	Carbon Dioxide
DIA dia	Diastolic



ECG ecg	Electrocardiogram
EEG eeg	Electroencephalogram
EMG emg	Electromyogram
ESIS	Electrosurgical Interference Suppression
EXT	External
FECG	Fetal Electrocardiogram
FHR1 FHR2	Fetal Heart Rate, Channel 1 Fetal Heart Rate, Channel 2
GND gnd	Ground
Hz	Hertz
Hgb	Hemoglobin
HLO hlo	High-Level Output
Multiview	Multi-Lead Electrocardiogram
N <sub>2</sub> O	Nitrous Oxide
NIBP nibp	Noninvasive Blood Pressure
O <sub>2</sub> AV	Oxygen Availability
O <sub>2</sub>	Oxygen
PaO <sub>2</sub>	Partial Pressure of Arterial Oxygen
PRESS press PRS	Pressure
PvO <sub>2</sub>	Partial Pressure of Mixed Venous Oxygen
Ref.	Oxygen reference gas port
RESP resp	Respiration
SDLC	Synchronous Data Link Control
·	



Arterial Oxygen Saturation as Measured by Pulse Oximetry
Mixed Venous Oxygen Saturation
Systolic
Temperature 1 Temperature 2 Temperature 3 Temperature 4
Temperature
Uterine Activity or Umbilical Artery
Umbilical Venous
Vacuum Connection
Oxygen Consumption
Volts
Watts