
IntelliVue TRx/TRx⁺ Transceivers

for the Philips IntelliVue Telemetry System with Smart-Hopping Technology

Notice

Operation of this equipment in the United States requires the prior coordination with a frequency coordinator designated by the Federal Communications Commission (FCC) for the Wireless Medical Telemetry Service.

Instructions for Use

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PHILIPS

Printing History

Notice

Equipment specifications are subject to alteration without notice. All changes will be in compliance with regulations governing manufacture of medical equipment.

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Philips IntelliVue Telemetry System with Smart Hopping Technology is compatible with:

Philips Information Center, software revision F.00
Philips TeleMon Companion Monitor, #A02/A03

About this Book

This book contains operating instructions for use of the IntelliVue TRx and TRx⁺ Transceivers as used with the Philips IntelliVue Telemetry System with Smart-hopping Technology. It also includes operational information for the Telemetry functions of the IntelliVue Information Center. The intended audience is the clinician who uses and/or teaches others to use the equipment in a healthcare environment. For operating information on other functionality of the Information Center, see *IntelliVue Information Center Instructions for Use*. For preventive maintenance, repair, and test methods for verification of device performance, refer to the *Philips IntelliVue Telemetry System Service Kit*.

This book does not address the Philips M2601B Transmitter or the M2600B Philips Telemetry System. For information on those products, refer to the manual *Philips Telemetry System Instructions for Use*.

Note—Use this product in conjunction with *Philips IntelliVue Information Center Instructions for Use* and *Online Help*, and with *Philips TeleMon A02/A03 Companion Monitor Instructions for Use*. See also the *Philips IntelliVue Telemetry Training Program*.

Document Conventions

Warnings

Warning

Warnings are information you should know to avoid injuring patients and personnel.

Cautions

Caution

Cautions are information you should know to avoid damaging your equipment and software.

Product Safety Information

Notes

Note—Notes contain additional information on use of the Philips IntelliVue Telemetry System.

Procedures

Procedures are indicated in text by the heading “Task Summary” followed by the following table:

Step	Action
1	
2	
3	

Bold Typeface

Objects of actions in procedures appear in **bold** typeface. Note the following example:

Select the **Standby** button.

Product Safety Information

The following general warnings and cautions apply to use of the Philips IntelliVue Transceivers in a Philips IntelliVue Wireless Network. Additional warnings and cautions specific to a particular feature are provided in the appropriate section.

General

Warning

For continued safe use of this equipment, it is necessary that the listed instructions are followed. Instructions in this manual in no way supersede established medical procedures.

Product Safety Information

Warning

Do not touch the patient, or table, or instruments, during defibrillation. The battery door must be closed during defibrillation. These steps protect the clinician from high defibrillator voltage.

Warning

This device is not to be used in the vicinity of electrosurgical units because use may interrupt or interfere with the transmission of signals from the transceiver.

Warning

This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide

Warning

Do not use patient cables with detachable lead wires that have exposed male pins. Electrocutation could result if these pins are plugged into AC power.

Warning

Use of product accessories (e.g., ECG leadsets, SpO₂ sensors) other than those prescribed by Philips could lead to patient injury.

Warning

To avoid strangulation, do not tie a pouch solely around the patient's neck.

Product Safety Information

**ECG/
Arrhythmia -
All Patients**

Warning

ECG SAFETY FOR ALL PATIENTS

Always confirm Information Center observations with clinical observation of the patient before administering interventions.

Every lead must be secured to an electrode on the patient. Conductive parts of electrodes must not contact earth or other conductive parts.

Philips recommends that you change the lead label only to reflect the physical placement of electrodes. This will ensure a match between the monitored lead and the label, and prevent any possible confusion.

When switching between EASI and standard monitoring, there is a loss of data for 30 seconds.

Warning

ST/AR ARRHYTHMIA SAFETY FOR ALL PATIENTS

During complete heart block or pacemaker failure (to pace or capture), tall P-waves (greater than 1/5 of the average R-wave height) can be erroneously counted by the arrhythmia algorithm, resulting in missed detection of cardiac arrest.

Learning/Relearning

- If you initiate learning during ventricular rhythm, the ectopics can be incorrectly learned as the normal QRS complex. This can result in missed detection of subsequent events of V-Tach and V-Fib.

- When using EASI ECG monitoring, Relearn happens automatically when there is a LEADS OFF technical alarm. If learning takes place during ventricular rhythm, the ectopics can be incorrectly learned as the normal QRS complex. This can result in missed detection of subsequent events of V-Tach and V-Fib. Be sure to check the beat labels and initiate a relearn to correct. Therefore, when a technical alarm is generated:

1. Respond to the technical alarm [for example, reconnect the electrode(s)].
 2. Ensure that the arrhythmia algorithm is labeling beats correctly.
-
-

Product Safety Information

**ECG/
Arrhythmia -
Paced
Patients**

Warning

ECG SAFETY FOR PACED PATIENTS

The output power of the transceiver and other sources of radio frequency energy, when used in the proximity of a pacemaker, can be sufficient to interfere with pacemaker performance. Due to the shielding effects of the body, internal pacemakers are somewhat less vulnerable than external pacemakers. However, caution should be exercised when monitoring any paced patient.

In order to minimize the possibility of interference, position electrodes, electrode wires, and the transceiver as far away from the pacemaker as possible.

Consult the pacemaker manufacturer for information on the RF susceptibility of their products and the use of their products with the Philips IntelliVue Telemetry System. See the *IntelliVue Information Center Instructions for Use* for additional information on monitoring paced patients.

Warning

ST/AR ARRHYTHMIA SAFETY FOR PACED PATIENTS

It is possible that pacemaker pulses will not be detected when the ECG analog output of a defibrillator or telemetry unit is plugged into a bedside monitor. This can result in the arrhythmia algorithm's failure to detect pacemaker non-capture or asystole.

Some pace pulses can be difficult to reject. When this happens, the pulses are counted as a QRS complex, and could result in an incorrect HR and failure to detect cardiac arrest or some arrhythmias. Keep pacemaker patients under close observation.

-- During complete heart block or pacemaker failure (to pace or capture), tall P-waves (greater than 1/5 of the average R-wave height) can be erroneously counted by the arrhythmia algorithm, resulting in missed detection of cardiac arrest.

-- When arrhythmia monitoring paced patients who exhibit only intrinsic rhythm, the monitor can erroneously count pace pulses as QRS complexes when the algorithm first encounters them, resulting in missed detection of cardiac arrest.

For patients who exhibit intrinsic rhythm only, the risk of missing cardiac arrest can be reduced by monitoring these patients with the low heart rate limit at or slightly above the basic/demand pacemaker rate. A low heart rate alarm alarms you when the patient begins pacing. Proper detection and classification of the paced rhythm can then be determined.

-- When an external pacemaker is being used on a patient, arrhythmia monitoring is severely compromised due to the high energy level in the pacer pulse. This can result in the arrhythmia algorithm's failure to detect pacemaker non-capture or asystole.

Product Safety Information

SpO₂

Warning

SpO₂ SAFETY

Always confirm Information Center observations with clinical observation of the patient before administering interventions.

Prolonged, continuous monitoring can increase the risk of changes in skin characteristics, such as irritation, reddening, blistering or pressure necrosis, particularly on patients with impaired perfusion and varying or immature skin morphology. Specific attention must be given to sensor site inspection for changes in skin quality, proper optical path alignment and attachment. Check the application site at regular intervals and change the site if any compromise in skin quality should occur. More frequent checking can be required due to an individual patient's condition.

Using a sensor during MR imaging can cause severe burns. To minimize this risk, ensure that the cable is positioned so that no inductive loops are formed. If the sensor does not appear to be operating properly, remove it immediately from the patient.

Do not use disposable sensors on patients who exhibit allergic reactions to the adhesive.

Injected dyes such as methylene blue or intravascular dyshemoglobins such as methemoglobin and carboxyhemoglobin can lead to inaccurate (over-estimated) measurements.

Interference leading to inaccurate measurements can be caused by:

- High levels of ambient light (Hint: cover application site with opaque material)
 - Electromagnetic interference
 - Excessive patient movement and vibration.
-
-

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1

Basic Operation

This chapter introduces the Philips IntelliVue Telemetry System with Smart-hopping Technology and the IntelliVue TRx and TRx⁺ Transceivers. It includes the following sections:

- The Philips IntelliVue Telemetry System. 1-2
- The IntelliVue Transceiver. 1-3
- Turning the Transceiver On 1-15
- Testing IntelliVue Transceiver Functionality 1-17
- Battery Information. 1-19
- Pouch Use 1-24
- Transceiver Use with TeleMon A02/A03. 1-27
- Transceiver Use with TeleMon A02/A03. 1-27

The Philips IntelliVue Telemetry System

The Philips IntelliVue Telemetry System with Smart-hopping Technology provides ambulatory and bedside monitoring of ECG and SpO₂ parameters over the radio frequency (RF) spectrum newly allocated for medical telemetry applications by the Federal Communications Commission (FCC). The System enables clinically significant data and control information for adult and pediatric patients in healthcare facilities to be received from and sent to the transceiver, a patient-worn device, via a bi-directional RF link over the Wireless Medical Telemetry Service (WMTS) spectrums 1395-1400 MHz and 1427-1432 MHz.

The System uses smart-hopping technology to dynamically manage the RF spectrum utilization per transceiver, thus allowing a virtually unlimited number of simultaneously operating transceivers within the Philips IntelliVue Telemetry System. The frequency-agile system changes frequency without user involvement or awareness whenever interference occurs.

The System encompasses a number of individual units which connect together to form a complete method of transporting ambulatory patient data to a central repository for subsequent distribution to clinical staff. An installation typically consists of the following components:

- M4841A Transceivers, bi-directional patient-worn devices
- M4842A Access Points (AP), centers for bidirectional communication between the transceivers and the Information Center.
- IntelliVue Wireless Network (IWN) infrastructure (including M4843A Access Point Controllers, M4844A Sync Units, M4845A Power Supply Units)
- M3150A IntelliVue Information Center for centralized monitoring
- M3154A IntelliVue Database Server (optional) for centralized data management
- M2636A TeleMon A02/A03 Companion Monitor (optional) for local display, NBP measurement and local alarms.

The network interconnects Access Points to the Information Center and other central equipment via the same network that connects IntelliVue bedsides to the Information Center. Access points receive signals, and unlike traditional antenna systems, can communicate bidirectionally. Access Points are powered, controlled and managed remotely via the IWN.

System Features

- Full patient mobility within the areas defined by the wireless coverage provided by multiple Access Points.
- Expanded geographic coverage area for a given patient assigned to an IntelliVue Clinical Network. Physiological data is transported from the transceiver; a reverse data channel enables data to be transported to the transceiver.
- 3-minute Alarm Pause/Suspend initiated at the transceiver.
- Standby mode when a patient is away from the unit and not being monitored by the Philips IntelliVue Telemetry System.
- Find Device feature for locating a lost transceiver within the coverage area.
- Access Points operating concurrently with the networked bedside wireless capability while sharing some of the ICN infrastructure.
- Use of the radio spectrums newly allocated by the FCC specifically for medical telemetry applications.
- Connectivity to TeleMon for display of patient measurements - including NBP - at the bedside.

diagram to come

System Information Flow/Smart-hopping

The IntelliVue Transceiver

The Philips IntelliVue transceiver is a patient-worn device for monitoring ECG and SpO₂ on adult and pediatric patients in the IntelliVue Telemetry System

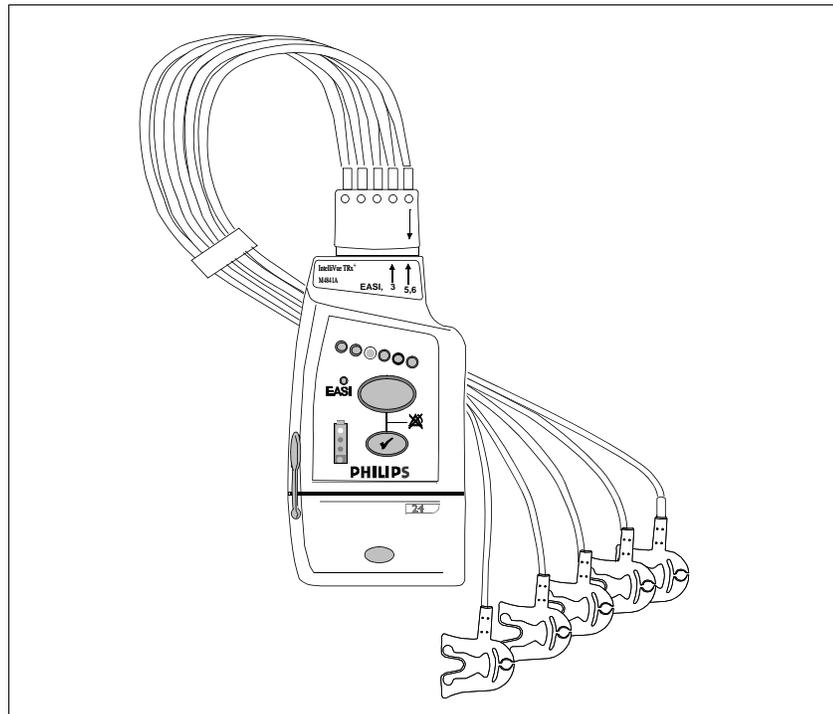
The IntelliVue Transceiver

with Smart-Hopping Technology, a cellular infrastructure network. The transceiver combines traditional transmitter features with two-way communication capability with the IntelliVue Information Center. The transceiver is designed to be easy for clinicians to use and comfortable for patients to wear. Colored labels provide departmental identifiers. The leadsets are optimized for ambulating patients, with a cable length of 79 cm (30 inches). Protective covers prevent dirt from accessing unused ECG and SpO₂ cable ports, thus simplifying cleaning.

The transceiver is available in two models, the ECG only called the IntelliVue TRx, and the ECG-SPO2 version, called the IntelliVue TRx⁺. The models are listed below and illustrated on the following pages in this chapter. Subsequent tables describe the buttons, indicators, labels, ports, safety symbols & other markings, and auditory information signals of the transceiver respectively.

Transceiver Model (M4841A)	Measurements
IntelliVue TRx	ECG
IntelliVue TRx ⁺	ECG, SpO ₂

The transceiver comes with a start-up kit of batteries, electrodes, and pouches.



IntelliVue TRx Transceiver - ECG only

Note—The IntelliVue Transceiver and M2601B Transmitter are similar in appearance. If your hospital uses both, you can distinguish between them by:

- *Name on the front of the device*
- *Label background color (pale gray for transceivers, dark gray for transmitters)*

**Transceiver
Features**

- Clinician-selectable 5-lead Standard or EASI leads in same device, at the bedside
- 6-leadset with two V leads for diagnosing multiple cardiac abnormalities, including wide-QRS complex tachycardias and acute myocardial ischemia/infarction
- Powered by two AA Alkaline batteries
- Spot-Check SpO₂ without using any control buttons

The IntelliVue Transceiver

- FAST-SpO₂ (Fourier Artifact Suppression Technology) for improved motion artifact rejection and low-perfusion performance
- Audio feedback for Spot Check SpO₂ completion and other common tasks
- Simultaneous operation in system with M2601A Transmitter
- Two sizes - smaller ECG only version and larger ECG/SpO₂ version
- Battery gauge on transceiver and, if configured, at Information Center
- Colored labels provide clinical unit identifiers.
- Leadsets are optimized for ambulating patients, with a cable length of 79 cm (30 in).
- Gunk guards prevent debris from accessing unused ECG and SpO₂ cable ports and the unused TeleMon/Service port, thus simplifying cleaning.
- Pouch with clear front and flap.

Use with Information Center

The bi-directional capability enables remote control from the Information Center of the following transceiver operations:

- From the Telemetry Setup Window:
 - SpO₂ measurement mode (Spot Check, Continuous, or Off)
 - Display and storage of real-time pleth wave (enable/disable)
 - Volume of audible transceiver information signals
 - Find device
 - Suppression of SpO₂ technical alarms during NBP measurement
- From the Patient Window
 - Standby mode
 - Filter bandwidth for ST measurement on/off
 - Alarm Pause/Suspend (enable/disable)
- From Unit Settings
 - Display of battery gauge (enable/disable)
 - 3-wire Lead Selection

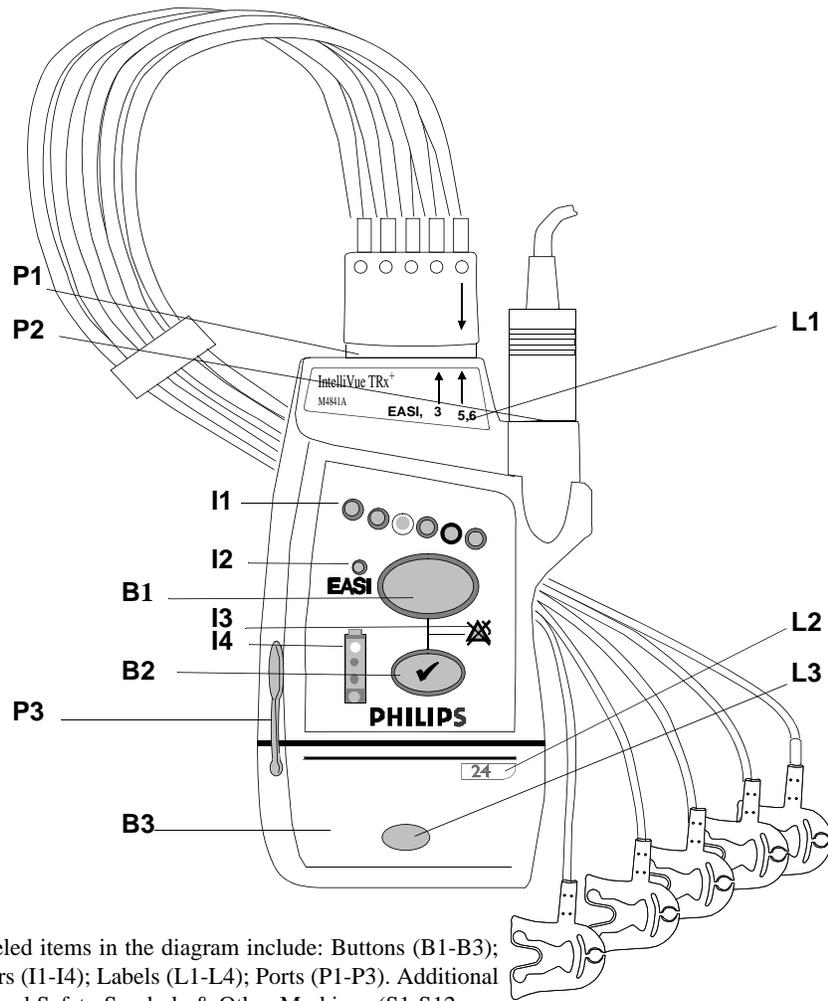
The system supports Own Bed Overview, the pairing of a telemetry bed with an IntelliVue Patient Monitor (Release B or higher) for a single patient. Own Bed Overview provides the telemetry-monitor data (waveforms, numerics and alarms) in an integrated form both on the bedside monitor and at the IntelliVue Information Center.

Use with TeleMon A02/A03

The transceiver can employ the full functionality of the TeleMon A02/A03 companion monitor, including NBP measurement and local display of alarms. Connection is made through an interface cable, or tether, at the TeleMon service

port. Please refer to the *TeleMon A02/A03 Instructions for Use* for general operating instructions and “Transceiver Use with TeleMon A02/A03” on page 1-27 for an operational summary.

Transceiver Controls - Front

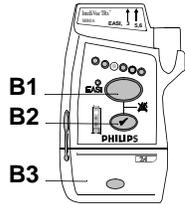


The labeled items in the diagram include: Buttons (B1-B3); Indicators (I1-I4); Labels (L1-L4); Ports (P1-P3). Additional Labels, and Safety Symbols & Other Markings (S1-S12, appear on the back of the transceiver.

IntelliVue TRx⁺ Transceiver - Front View

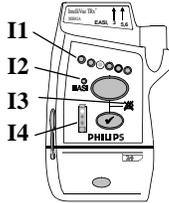
The IntelliVue Transceiver

Buttons



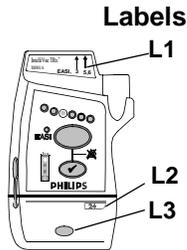
Callout	Button	Definition
B1		<p>Telemetry Button: Depending on configuration, directs the Information Center to generate a Nurse Call alarm, remote recording, Nurse Call alarm and recording, or none. See “Patient-Configurable Settings in Telemetry Setup” on page 6-3.</p> <p><i>Note</i>—Delayed recordings generated by the Telemetry button are stored in Alarm Review at the Information Center.</p> <p>When pressed simultaneously with the Check button, turns Alarm Suspend/Pause on/off (not when tethered to TeleMon). See “Suspending/ Pausing Alarms” on page 2-2.</p>
B2		<p>Check Button. Initiates a Status Check of the Transceiver. See “Status Check” on page 1-18.</p> <p>When pressed simultaneously with the Telemetry Button, turns Alarm Suspend/Pause on/off (not when tethered to TeleMon). See “Suspending/ Pausing Alarms” on page 2-2.</p> <p>Silences the Find Device tone. See “Telemetry Controls in the Patient Window” on page 6-2.</p>
B3	Power On/Off	<p>Battery Compartment. Insertion of batteries turns transceiver power on; removal of batteries turns power off. See “Turning the Transceiver On” on page 1-15.</p>

Indicators

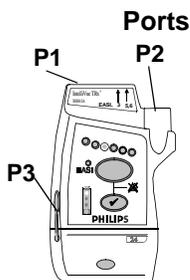


Callout	Indicator	Definition
I1		<p>Lead Indicator. Illuminates momentarily during leadset insertion to indicate attached leads.</p> <p>Illuminates when Check button is pressed to indicate attached leads.</p> <p>During a Leads Off condition, illuminates to indicate the lead(s) that need to be reapplied.</p> <p>Momentarily illuminates three alternate lights, indicating the transceiver has no Equipment Label assigned.</p>
I2		<p>EASI Indicator. Illuminates momentarily upon insertion of leadset in EASI position.</p> <p>Illuminates when Check button is pressed if EASI is in use.</p>
I3		<p>Alarms Suspend/Pause Indicator. Illuminates during 3 minute alarm pause initiated at transceiver or Information Center.</p>
I4		<p>Battery Gauge. Illuminates when the EHck button is pressed to indicate the amount of power remaining in the batteries. Valid only for recommended battery type. See “Checking the Battery Power Level” on page 1-22.</p>

The IntelliVue Transceiver



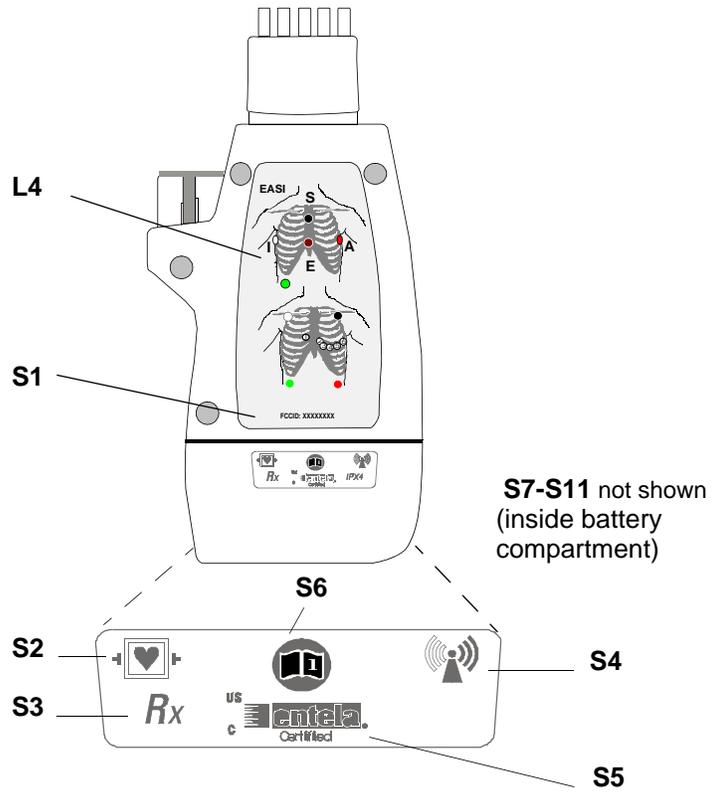
Callout	Label	Definition
L1		Leadset Insertion Guide. Assist in aligning the ECG cable for different leadsets. See “Connecting the ECG Cable” on page 3-19. <i>Note</i> —If your unit uses only one monitoring configuration, the transceiver may have special "lock out" plugs that allow only one way to insert the leadset.
L2		Device Identification Label. Identifies the device within the IntelliVue Wireless Network.
L3		Unit Identification Label. Uses one of seven color-coded labels to identify a clinical unit.



Callout	Definition
P1	ECG Leadset Port. Connection for 3-wire or 5-wire leadset.
P2	SpO₂ Sensor Port. Connection for SpO ₂ sensor. (IntelliVue TRx ⁺ only)
P3	TeleMon/Service Port. Connection for cable to TeleMon Companion Monitor or to Service Tool.

Note—Ports can be covered with protective covers (gunk guards) when not in use. See “Gunk Guards” on page -4.

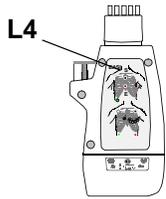
Transceiver Controls - Back



IntelliVue TRx+ Transceiver - Back View

The IntelliVue Transceiver

Labels



Callout	Definition
L4	Electrode Placement Diagrams (See “Positioning ECG Electrodes” on page 3-8.)

Safety Symbols & Other Marks

Callout	Label	Definition
S1	FCCID: XXXXXXXX	Federal Communications Commission (FCC) (PTT) label
S2		Patient connections are protected against defibrillation (DEFIBRILLATION-PROOF) and are a TYPE CF APPLIED PART.
S3	Rx	Prescription device.
S4		Non-Ionizing Radiation. Interference to electronic equipment may occur in the vicinity of devices marked with this symbol.
S5		Complies with all applicable Canadian and American standards.

Callout	Label	Definition
S6		Follow operating instructions.
S7		Philips Catalog Number
S8		Serial Number (inside battery compartment). Needed to identify the equipment during a call to the Response Center.
S9		MAC Address of device
S10		Date of manufacture
S11		Battery Polarity

Auditory Information Signals

The transceiver produces auditory feedback to inform you of measurement and battery conditions. Adjustable sounds can be set to 5 different volume levels or turned off per patient at the Information Center (see “Patient-Configurable Settings in Telemetry Setup” on page 6-3). Adjustable sounds include Check

The IntelliVue Transceiver

button Standby functions, SpO₂ measurement complete, outside of coverage area warning, and the pulse detection tone.

Auditory Information Signal	Definition	Volume/Mute Adjustable
Single Tone	Self Test passed	no
	SpO ₂ Spot Check measurement successful	yes
Single Tone, low pitch	Pulse detection successful (when locally initiated)	yes
Double Tone	Self Test failed	no
	SpO ₂ Spot Check measurement failed	yes
Double Tone repeated every 5 seconds	Out of range	yes
Continuous Double Tone, two pitches	Find Device	no
Single Tone (when Check button pressed)	Transceiver is associated with sector at Information Center (after Standby).	yes
Double Tone (when Check button pressed)	Transceiver not associated with sector at Information Center (after Standby).	yes
Double Tone and all indicators flashing	No equipment label is assigned from Information Center. No monitoring.	no
Fast Double Tone and alternate Leads Off indicators flashing	Equipment label is received from Information Center and is awaiting local acknowledgment by Check button press.	no

**Transceiver
Safety
Information**

Warning

If another radio medical device is operating at the same frequency as an IntelliVue Transceiver, it is possible that either device will not function properly.

Warning

Although the transceiver is shielded against Electromagnetic Interference (EMI), avoid the use of other electrically radiating devices in close proximity to the transceiver because they might interfere with transceiver operation.

Warning

Place the transceiver in a pouch or over clothing, or both, during patient use. The transceiver should not touch the patient's skin during use.

Turning the Transceiver On

Warning

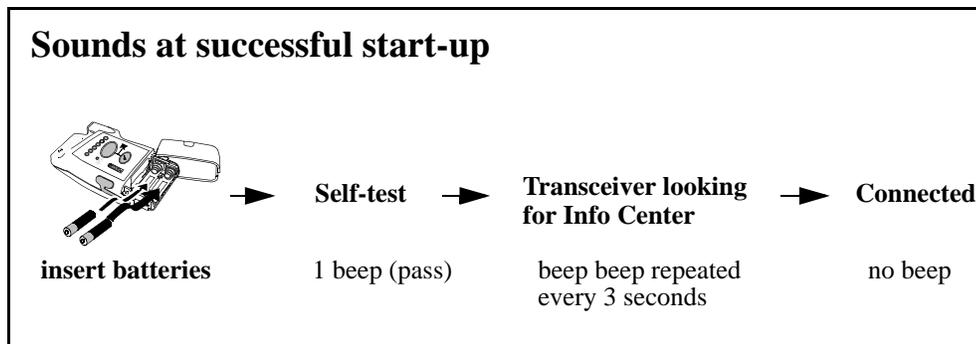
Arrhythmia relearning is initiated whenever the transceiver is powered down for one minute or longer. Be sure to check your patient's arrhythmia annotation for accuracy whenever relearn has occurred.

The transceiver is powered by two AA alkaline batteries. To turn the transceiver on, insert both batteries. Remove the batteries to turn the power off.

The configuration data set by the Service Provider prior to transceiver use is retained after battery removal.

Turning the Transceiver On

When the transceiver is turned on, all indicators illuminate briefly and a sequence of sounds indicates the instrument is ready for use. You should hear a single beep indicating that the self test was passed, followed by a series of double beeps while the transceiver attempts to associate with the Information Center. The cessation of sounds indicates a successful association. If you hear a single double beep or any other sound sequence, the automatic self-test of the device has not passed, or there is another problem. Contact your Service Provider.



Turning the Transceiver Off

Turn off the transceiver by removing the batteries. A NO SIGNAL technical alarm will be in effect at the Information Center until the device is turned on or until Standby is initiated.

Telemetry monitoring can be turned off in the following ways:

- Manually, by activating Monitoring Standby at the Information Center (see “Standby Mode” on page 2-5).
- Automatically, if Transceiver RF Auto Shutoff is enabled and there is no ECG signal for 10 minutes.

Note—Turning off telemetry monitoring does not turn off the transceiver.

Auto Shutoff

Automatic Shutoff causes the transceiver to stop broadcasting a radio signal if there is no ECG signal for 10 minutes. This prevents interference with other transceivers in use. The technical alarm text at the Information Center is Transmitter Off. To conserve battery power, remove batteries.

To restart monitoring, insert batteries if necessary, attach leads to the patient and press the Check button to verify association with the Information Center.

Testing IntelliVue Transceiver Functionality

There are two tests of IntelliVue Transceiver functionality:

- **Self Test** - performed automatically each time the transceiver is turned on
- **Status Check** - initiated manually by the clinician.

Self Test

Warning

Do not use the transceiver for patient monitoring if it fails the Power On Self Test.

A self test of the transceiver functions is automatically performed each time that the transceiver is turned on (that is, batteries are inserted).

Self Test Status	Auditory Signal (if configured on)	Visual Indicators
Passed	Single beep	All indicators illuminate for 3 seconds
Failed	Double beep	One or more indicators do not light up.

In Case of Failure

If any portion of the self test fails, the transceiver will attempt to report the failure to the monitoring system. In case of failure, use another transceiver, and contact your Service Provider.

Status Check

You can check the status of the transceiver indicators at any time.

To initiate a Status Check, use the following instructions.

Step	Action
1	<p>Press the Check button.</p> <p>The following indicators should illuminate for as long as the Check button is depressed.</p> <ul style="list-style-type: none">• Battery gauge• Type of leadset• EASI (if in use)
2	<p>If one or more of the expected indicators do not light up, check the following:</p> <ul style="list-style-type: none">• Lead block insertion. Make sure the leadset is correctly inserted in the transceiver and the orange line at the base of the cable is not visible (see “Connecting the ECG Cable” on page 3-19).• Power and position of batteries (see “Checking the Battery Power Level” on page 1-22)• Lead positions and connections (see “Verifying Electrode Connections” on page 3-22) <p>If there is still a problem, contact your Service Provider for assistance.</p>

Battery Information

Battery Safety Information

Warning

Use Duracell MN 1500 AA 1.5V Alkaline batteries to ensure specified performance. Outdated, mismatched or poor-quality batteries can give unacceptable performance (e.g., insufficient Battery-Low warning time). The use of fresh high-quality alkaline batteries is strongly recommended.

Batteries should be removed from the transceiver at the end of the battery's useful life to prevent leakage.

If battery leakage should occur, use caution in removing the battery. The leaked substance may cause eye or skin irritation. Avoid contact with skin. Clean the battery compartment according to instructions in "Chapter 7. Maintenance & Troubleshooting". Wash hands.

Certain failure conditions, such as short circuits, can cause a battery to overheat during normal use. High temperatures can cause burns to the patient and/or user. If the transceiver becomes hot to the touch, place it aside until it cools. Then remove the batteries and discard them. Have the transceiver operation checked by your Service Provider to identify the cause of overheating.

The battery door must be closed during defibrillation.

If you receive a BATTERY LOW alarm, the batteries must be promptly replaced. A "Battery Low" condition that is not corrected will result in a transceiver shutdown and cessation of monitoring.

Battery Information

Disposal of Batteries

Caution

The batteries must be removed if a transceiver will be stored for an extended period of time.

Important—When disposing of batteries, follow local laws for proper disposal. Dispose of batteries in approved containers. If local regulations require you to recycle batteries, recycle batteries in accordance with those regulations.

Battery Life

Battery life is dependent upon:

- Condition of the batteries
- Parameters being monitored - ECG only, ECG and Spot Check SpO₂, or ECG and Continuous SpO₂.

By observing the following guidelines, you can optimize battery life in the transceiver:

- REMOVE the batteries when the transceiver is not in use.
- Disconnect the SpO₂ extender cable (if used). (When the SpO₂ sensor is disconnected, the SpO₂ functionality is automatically powered down, but an extender cable will continue to drain power from the SpO₂ electronics.)

Inserting/ Removing Batteries

Warning

Arrhythmia relearning is initiated whenever the transceiver is powered down for one minute or longer. Be sure to check your patient's arrhythmia annotation for accuracy whenever relearn has occurred.

Caution

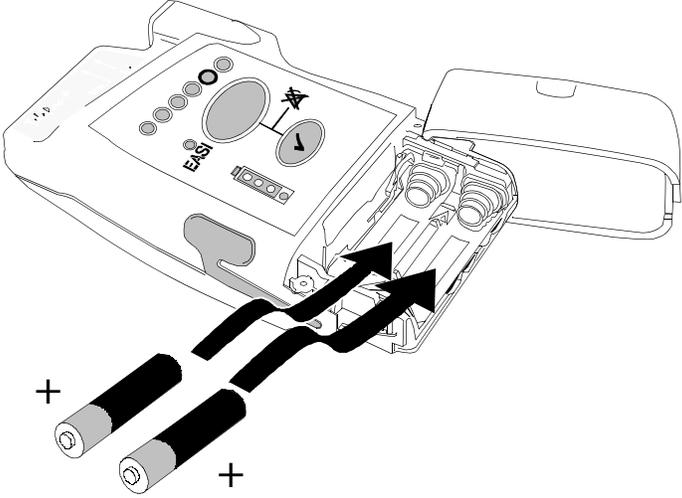
Remove the batteries before storing a transceiver for an extended period of time.

The battery compartment is located at the bottom of the transceiver behind a swinging door. It accommodates a pair of AA 1.5V Alkaline batteries. Only this type of disposable battery shall be used.

Important—Do not use rechargeable batteries. Use of this type of battery will adversely affect:

- Battery gauge performance
- Battery low warnings
- Battery life performance

Insert batteries into the transceiver using the following procedure.

Step	Action
1	Open the battery compartment by swinging the compartment door 90° counterclockwise into an open hinged position.
2	<p>Insert two AA 1.5V Alkaline batteries, matching the polarity with the +/- indications inside the compartment.</p>  <p><i>Note</i>— Both batteries are inserted with the + polarity in the same direction.</p>

Battery Information

Step	Action
3	Close the battery compartment door.
4	Listen for the start-up sounds. Watch for the indicators on the front of the transceiver to illuminate briefly.
5	Connect/reconnect the patient cables to the transceiver.

Removing the Batteries

Batteries should be changed in sets, that is, if you change one battery, change them both. To remove the batteries, simply open the battery compartment door and push from the opening at the back of the compartment to pop the batteries out. Transceiver settings (ECG leadset type, SpO₂ mode, volume, etc.) are retained indefinitely when the batteries are removed.

If you remove good batteries to turn off the transceiver, keep them together as a set for later re-use so that both batteries will have the same level of power remaining.

Batteries should be removed when the transceiver is not in use or is being stored. **DO NOT "STORE" BATTERIES BY LEAVING THEM IN THE INCORRECT POLARITY POSITION IN THE TRANSCEIVER.**

Be careful not to short circuit the batteries. Short circuits are caused when a piece of metal touches both the positive and negative terminals simultaneously (for example, by carrying batteries in a pocket with loose change). More than a momentary short circuit will generally reduce the battery life. In case of a short circuit, discard both batteries in a pair, or just the shorted one if the batteries are new.

Checking the Battery Power Level

When the Check button is pressed, the battery gauge on the transceiver indicates the battery power level. It is reliable only when specified batteries (i.e., AA 1.5V Alkaline) are used. The battery gauge is also displayed in the Patient Sector at the Information Center to enable you to closely monitor battery status, for example, at change of shift.

Important— In the following table, battery life times are based on Duracell MN 1500 batteries. Battery life for other brands may be different.

Battery Gauge	Approximate Battery Life Remaining	Approximate Operating Time Remaining	Functionality
4 green indicators	> 75%	> 34.7 hours	Normal operation
3 green indicators	> 50%	> 23.1 hours	Normal operation
2 green indicators	> 25%	> 11.6 hours	Normal operation
1 green indicator	25% to Low Battery level	> 15 minutes	Normal operation
1 red indicator	Battery Low level to Replace Battery level	< 15 minutes	SpO ₂ disabled
no indicator	Replace Battery level (Check batteries for correct polarity)	none	Transceiver shutdown/ RF shutdown

To check the power level:

Step	Action
1	Press the Check button to determine the level.
2	<p>If no indicators flash:</p> <ol style="list-style-type: none"> 1. Check that the batteries are inserted properly. 2. Replace both batteries. 3. If there are still no indicators on the battery gauge, contact your Service Provider. <p>If the indicators illuminate but do not behave as described above, the transceiver has malfunctioned. Contact your Service Provider.</p>

Briefing the Patient

Warning

Patients should be instructed not to open the battery cover while the transceiver is in use.

If the Telemetry button has been configured to generate a Nurse Call, remote recording, or both, instruct the patient to use the button when needed.

Note—If desired, you can turn off patient use of the button at the Information Center. See “Patient-Configurable Settings in Telemetry Setup” on page 6-3.

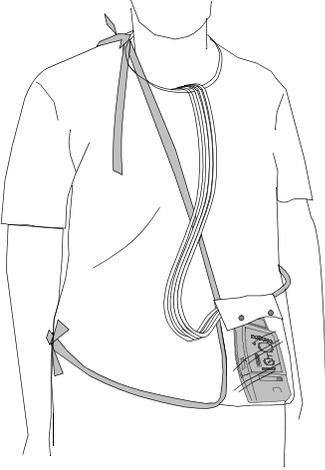
Pouch Use

The transceiver is not designed for direct contact with the patient’s skin. During normal use, the transceiver should be worn over clothing, in a pocket or, preferably, in a pouch. The carrying pouch is an appropriate means for holding the transceiver.

Securing the Pouch

Step	Action
1	<p>Secure the pouch on the patient with upper ties around the patient's head and arm, and lower ties around the patient's lower torso.</p> <hr/> <p>Warning</p> <p>To avoid strangulation, do not tie a pouch solely around the patient's neck.</p> <hr/>
2	<p>Insert the transceiver into the pouch with lead wires and SpO2 sensor cable, if used, exiting from the same side.</p> <div data-bbox="846 873 1154 1308" data-label="Image"> <p>The diagram shows a top-down view of a patient's head and neck area. A rectangular pouch is secured around the neck with two horizontal ties. A transceiver device is attached to the front of the pouch. Several cables are connected to the top of the transceiver: a bundle of four cables on the left, a single cable on the right, and a thicker cable at the bottom. The cables are shown exiting from the side of the pouch. The transceiver has a small display screen and several buttons.</p> </div> <p><i>Important</i>—Do not coil the cables inside the pouch. They are part of the wireless system, and need to be freely exposed.</p>

Briefing the Patient

Step	Action
3	Fold the flap down and snap closed.
4	Check that the patient is comfortable wearing the pouch with transceiver. 

Showering

Warning

Signal quality and leads off detection may be compromised when showering due to significant patient movement. Appropriate clinical precautions must be taken.

The transceiver can be used to monitor a patient in the shower, but only when placed inside a Philips carrying pouch with the flap closed and the snaps secured. The combination of the transceiver and pouch will withstand showering for up to 10 minutes.

**Drying the
Transceiver
after
Showering**

After showering, perform the following steps to continue monitoring:

1. Pat dry the leadset connections at the electrodes.
2. Wipe the lead wires with care.
3. If wet, dry the outside of the transceiver with a non-lint producing cloth.
4. If wet, wipe the inside of the battery compartment dry. Dry the batteries.
5. If wet, disconnect the ECG lead block and shake out any water. Dry the connector pin area with a cotton swab.

Note—The transceiver should not be used for monitoring if the battery compartment is wet. Remove the batteries and wipe the compartment dry before continued monitoring use.

**Accidental
Wetting**

If the transceiver is accidentally immersed in liquid for up to 5 minutes, no damage to the device and no electrical safety issues for the patient will result. Remove the device, dry it off, and follow the procedure for cleaning/disinfection or cleaning/cross-infection prevention under “Troubleshooting” on page 7-15 as appropriate.

Transceiver Use with TeleMon A02/A03

When tethered to TeleMon, the following transceiver operational behavior will be in effect.

Alarms

- 3 minute alarm pause/suspend can be initiated only from TeleMon, not from the transceiver or from the Information Center. The Alarm Suspend/ Pause indicator on the transceiver will accurately reflect the current state of alarm pause.
- Standby mode is not available.

ECG Operation

- Vb, the second V-lead in 6-wire lead-set, is not supported.
- After a change in leadset, the TeleMon returns to the default ECG settings, and arrhythmia relearn occurs automatically. Be sure to check the monitoring leads after you switch leads.

SpO2 Operation

Transceiver Use with TeleMon A02/A03

- SpO₂ is always in continuous mode.
- Changes in SpO₂ mode do not take effect until after the transceiver is disconnected from TeleMon. Mode settings are defined in the following table:

Mode at TeleMon	Mode at Disconnected Transceiver
Continuous	Continuous
5-min.	Continuous
1-min.	Continuous
Manual	Spot Check

- After a change in SpO₂ sensor, TeleMon returns to the default ECG settings, and arrhythmia relearn occurs automatically. Be sure to check the monitoring leads after you change the sensor.

Transceiver Operational Controls & Indicators

- When you press the Telemetry button, a Nurse Call alarm, recording, alarm and recording, or neither will be generated, depending on the configuration at the Information Center.
- When you press the Check button, the transceiver battery gauge indicates full power, regardless of actual battery strength.
- When you press the Telemetry and Check buttons together, there is no action; a 3-minute alarm pause/suspend can be initiated only from TeleMon. The alarm pause indicator on the transceiver will accurately reflect the current state of alarm pause.
- When the transceiver is connected to TeleMon, the battery gauge on the transceiver and displayed at the Information Center always indicates "full" regardless of actual battery power. To update the gauge, disconnect the transceiver and wait several seconds for the updated battery strength to be displayed.

Defibrillation

- In the event of patient defibrillation, it may take several seconds for the ECG trace to reappear on the screen.

2 Alarms

This chapter describes how to pause/suspend alarms temporarily. It also lists Physiologic (Patient) Alarms and Technical (Inoperative Conditions) Alarms. Both types of alarms are listed alphabetically.

- Alarm Indicators 2-2
- Suspending/Pausing Alarms 2-2
- Standby Mode 2-5
- Alarm Behavior with Own Bed Overview 2-7
- Physiologic Alarms 2-9
- Technical Alarms (INOPs) 2-14

Alarm Indicators

A description of visual and auditory information signals for patient and technical alarms on the Information Center is located in the *IntelliVue Information Center Instructions for Use* and the *Information Center Online Help*. The Information Center documentation also includes the default alarm settings and physiological alarm limit ranges

Testing Alarm Indicators

The visual alarm information signal on the transceiver is the Alarms Suspend icon. During self test, the Alarm Suspend indicator illuminates, and a single tone indicates association with the Information Center. These positive test results indicate that the Alarm Suspend icon on the transceiver is functioning correctly (see “Status Check” on page 1-18).

Suspending/Pausing Alarms

Warning

If the Alarms Suspend indicator on the transceiver remains illuminated after the button combination to unsuspend alarms is pressed, a the transceiver malfunction may have occurred. Alarms resume automatically after the 3 minute suspension period, or you can resume them manually at the Information Center. The transceiver should be replaced, and the malfunctioning unit should be sent to your Service Provider.

All alarms for a patient can be suspended/paused from the Information Center, from the TeleMon Companion Monitor, or, depending on transceiver configuration, from the transceiver itself. The Alarm Suspend/Pause duration is fixed at 3-minutes. Alarms automatically resume after 3 minutes, and can be reactivated manually earlier.

Suspending/Pausing Alarms

If connected to TeleMon, alarms can be suspended only from TeleMon, and not from the Information Center, and the Alarms Suspend icon on the transceiver is lit (see “Transceiver Controls - Front” on page 1-7), and an ALARMS SUSPENDED message appears at TeleMon and the Information Center.

Important—Patient monitoring (display of patient waveforms and numerics) continues for the duration of Alarm Suspend/Pause.

Step	Action
1	<p>To activate Alarm Pause/Suspend at the transceiver, press the Telemetry and Check buttons simultaneously.</p> <p>While alarms are suspended:</p> <ul style="list-style-type: none">• The transceiver illuminates the Alarms Suspend icon.  <ul style="list-style-type: none">• The message ALARMS SUSPENDED (or ALARMS PAUSED) is displayed in the Patient Sector at the Information Center.
2	<p>For instructions on how to pause/suspend alarms from the Information Center, see the <i>IntelliVue Information Center Instructions for Use</i> and the <i>Information Center Online Help</i>.</p>

Suspending/Pausing Alarms

Resuming/ Unsuspending Alarms

Alarms will be resumed automatically after 3 minutes. You can cancel alarm suspend manually before the 3-minute period has expired from the transceiver (see following directions) or from the Information Center.

Step	Action
1	Press the Telemetry and Check buttons simultaneously. <ul style="list-style-type: none">• Auditory alarm indication at the transceiver is switched on.• The Alarm Suspend icon is turned off.• The message ALARMS SUSPENDED (or ALARMS PAUSED) is removed from the display.
2	Alternately, you can unsuspend alarms at the Information Center. See <i>IntelliVue Information Center Instructions for Use</i> or <i>Online Help</i> for directions.

Standby Mode

Standby mode is useful when the transceiver is temporarily removed from a patient or when a patient is intentionally moved out of range of an Access Point. Standby suspends monitoring so you won't get any patient alarms or waveforms. It also disables the out of range audio signal. Patient data and current settings are preserved during the Standby period.

Standby also serves to turn telemetry monitoring off when a patient is discharged. Patient data is not erased and unit default settings are not in effect until the discharge operation is performed. A bed should be put into Infinite standby until a new patient is connected to the transceiver. Monitoring can then be restarted by a click of the Resume Monitoring button.

Note—To discharge a patient:

1. Disconnect the patient.
2. Remove batteries from the transceiver.
3. Put bed in Standby.

You place a patient in standby mode at the Information Center. You can select the duration of the standby period (Infinite, 4, 3, 2, or 1 hours, 30, 20, or 10 minutes). The approximate time of resumption of monitoring will be displayed. To restart monitoring, click on **Resume Monitoring** in the Patient Sector.

Note—Unless you are discharging a patient, keep the leads attached until the patient is in Standby. If you remove the leads before putting a patient into Standby, you'll get an ECG LEADS OFF technical alarm, as well as reminders, if configured.

Initiating Standby

Step	Action
1	In the Patient Window or All Controls at the Information Center, select the Standby button.
2	Select the patient destination from the pre-defined list.

Standby Mode

Step	Action
3	Depending on your equipment configuration, select the duration of the standby period (30, 20 or 10 minutes; 2, 3 or 4 hours; or infinite).
4	Select the Suspend Monitoring button. This suspends all monitoring and displays the following messages in the Patient Sector: PATIENT LOCATION:xxx (for example, X-ray) and TELEMETRY STANDBY. The approximate time of resumption is also displayed.

Resuming Monitoring

Step	Action
1	If the standby period has expired when the patient returns to the unit , monitoring will resume automatically. To verify the resumption of monitoring, press the Check button . You should hear a single beep.
2	If the standby period has not expired when the patient returns to the unit , monitoring must be reactivated manually. Either click Resume Monitoring at the Information Center or press the Check button on the transceiver to establish reassociation. The audible tone (single beep) at the transceiver verifies that monitoring has resumed.

Note—When you take an EASI patient out of Standby, the lead settings will be reset to the Information Center’s default lead settings.

Alarm Behavior with Own Bed Overview

Both the IntelliVue Patient Monitor and the telemetry system source alarms. The following tables summarize alarm behavior when Own Bed Overview is used. For detailed information, see the *IntelliVue Patient Monitor Instructions for Use* and the *IntelliVue Information Center Instructions for Use*.

Alarm Pause/Suspend

When alarms are paused/suspended, the messages and types of alarms affected depend on where the pause/suspend was initiated.

If alarms are paused/suspended from....	these alarms are paused/suspended	and this message appears
Information Center	both bedside and telemetry measurements	Information Center: ALARMS PAUSED or ALARMS SUSPENDED Bedside: ALARMS OFF in Overview window and ALARMS PAUSED or ALARMS OFF on the monitor (depending on configuration)
IntelliVue Patient Monitor	bedside measurements only	Information Center: BED ALARMS PAUSED or BED ALARMS SUSPEND (depending on configuration) Bedside: ALARMS PAUSED or ALARMS OFF

Alarm Silence

When an active alarm is silenced, the types of alarms that are silenced depend on the alarm source and where the silence was initiated.

Alarm Source	Where Silenced	Effect at Paired Bedside	Effect at Information Center
Bedside alarm	Bedside	Alarm is silenced	Bedside alarm is silenced. There is no effect on telemetry alarms
Telemetry alarm	Bedside	No effect on telemetry alarms	No effect on telemetry alarms
Bedside and/or telemetry alarm	Overview Silence Control	Bedside or telemetry alarm is silenced	Bedside alarm is silenced (if Silence Overview Alarms is configured)
Bedside and/or telemetry alarm	Information Center	Bedside or telemetry alarm is silenced	Bedside or telemetry alarm is silenced

Note—If tethered to TeleMon, silencing an active alarm at TeleMon silences the alarm at TeleMon only. It has no effect on the paired bedside monitor or the Information Center.

Alarm/INOPs at the Information Center

The alarms and INOPs that are displayed, recorded and stored at the Information Center depend on the type of alarm.

Type of Alarm/INOP	Effect at Information Center
All ECG telemetry alarms and INOPs <i>Note</i> —ECG is generated from telemetry when paired.	Displayed, recorded (if configured), and stored
Bedside ECG INOPs and RESP INOPs	Ignored. Not displayed, recorded, or stored
Bedside non-ECG alarms and non-ECG INOPs	Displayed, recorded (if configured), and stored

Physiologic Alarms

Physiologic alarms indicate a life-threatening situation or a less urgent situation such as heart rate beyond limits. There are no physiologic alarm signals generated by the transceiver. **All physiologic alarms are generated at the IntelliVue Information Center, and all alarm signals must be acknowledged at the Information Center.**

Arrhythmia alarm chaining and other aspects of alarm behavior, such as alarm levels, setting alarm limits, customizing arrhythmia alarm settings on a per patient basis, switching individual measurement alarms on/off, and reviewing alarm messages, are described in *IntelliVue Information Center Instructions for Use*.

There are two levels of arrhythmia analysis available at the Information Center: Basic and Enhanced. Enhanced analysis includes Basic alarms.

Physiologic Alarms

In the table, Red (***) alarms are listed alphabetically, followed by the Yellow (***) alarms, the Yellow (*) arrhythmia alarms.

Physiologic (Patient) Alarms

Alarm Text	Priority	Condition	Source
***ASYSTOLE	Red	Asystole. No QRS for 4 consecutive seconds	ST/AR Basic & Enhanced Arrhythmia
*** BRADY yyy < xxx	Red	Extreme Bradycardia. HR less than extreme Brady HR Limit	ST/AR Enhanced Arrhythmia
*** DESAT	Red	Very Low SpO ₂ Saturation. SpO ₂ value below desaturation limit (10% or 10 "points" below low limit).	SpO ₂
*** EXTREME BRADY	Red	Extreme Bradycardia. HR less than extreme Brady HR Limit	ST/AR Basic & Enhanced Arrhythmia
*** EXTREME TACHY	Red	Extreme Tachycardia. HR greater than extreme Tachy HR Limit	ST/AR Basic & Enhanced Arrhythmia
*** TACHY yyy > xxx	Red	Extreme Tachycardia. HR greater than extreme Tachy HR Limit	ST/AR Enhanced Arrhythmia
*** VFIB/TACH	Red	Ventricular Fibrillation. Fibrillatory waveform for 4 consecutive seconds	ST/AR Basic & Enhanced Arrhythmia

Physiologic (Patient) Alarms

Alarm Text	Priority	Condition	Source
*** VTACH	Red	Ventricular Tachycardia. Sustained run of PVCs accompanied by a high heart rate	ST/AR Basic & Enhanced Arrhythmia
** NURSE CALL	Yellow	Patient or nurse button press on the transceiver (when configured for Nurse Call operation) Also initiated if the installation includes a paging system and if the Information Center is configured for paging upon receipt of Nurse Call signal.	Clinician-initiated at transceiver or by paging subsystem
** SpO ₂ HIGH	Yellow	High SpO ₂ . SpO ₂ value greater than high SpO ₂ Limit.	SpO ₂
** SpO ₂ LOW	Yellow	Low SpO ₂ . SpO ₂ value less than low SpO ₂ Limit.	SpO ₂
** SpO ₂ yyy > xxx or	Yellow	High SpO ₂ . SpO ₂ value greater than high SpO ₂ Limit.	SpO ₂
** SpO ₂ yyy < xxx or	Yellow	Low SpO ₂ . SpO ₂ value less than low SpO ₂ Limit.	SpO ₂
* HR HIGH	Yellow	High Heart Rate. HR greater than high HR Limit	ST/AR Basic & Enhanced Arrhythmia
* HR LOW	Yellow	Low Heart Rate. HR less than low HR Limit	ST/AR Basic & Enhanced Arrhythmia

Physiologic Alarms

Physiologic (Patient) Alarms

Alarm Text	Priority	Condition	Source
* HR yyy > xxx	Yellow	High Heart Rate. HR greater than high HR Limit	ST/AR Enhanced Arrhythmia
* HR yyy < xxx	Yellow	Low Heart Rate. HR less than low HR Limit	ST/AR Enhanced Arrhythmia
* IRREGULAR HR	Yellow	Irregular Heart Rate. Constantly irregular HR.	ST/AR Enhanced Arrhythmia
* MISSED BEAT	Yellow	Missed Beat. Beat omitted	ST/AR Enhanced Arrhythmia
* MULTI ST Lx, Ly	Yellow	Multi ST Leads exceeding Limit (EASI mode or when selected). Two ST leads (Lx=Lead X and Ly=Lead Y) exceed alarm limit elevation or depression for > 60 seconds	ST/AR Arrhythmia
* MULTIFORM PVCs	Yellow	Multiform PVCs	ST/AR Enhanced Arrhythmia
* NON-SUSTAIN VT	Yellow	Non-Sustained VT. Non-sustained Ventricular Tachycardia	ST/AR Enhanced Arrhythmia
* PACER NOT CAPT	Yellow	Pacer Not Capture. Missed beat with pace pulse (paced patient).	ST/AR Basic & Enhanced Arrhythmia

Physiologic (Patient) Alarms

Alarm Text	Priority	Condition	Source
* PACER NOT PACE	Yellow	Pacer Not Pacing. Missed beat without pace pulse (paced patient).	ST/AR Basic & Enhanced Arrhythmia
* PAIR PVCs	Yellow	Pair of PVCs.	ST/AR Enhanced Arrhythmia
* PAUSE	Yellow	Pause. No QRS for more than x seconds	ST/AR Enhanced Arrhythmia
* PVC > xx/min	Yellow	PVCs > xx/min. PVCs greater than Rate Limit	ST/AR Basic & Enhanced Arrhythmia
* R-ON-T PVCs	Yellow	R-on-T PVCs	ST/AR Enhanced Arrhythmia
* RUN PVCs	Yellow	Run PVCs. Run of PVCs length ≥ 2	ST/AR Enhanced Arrhythmia
* ST lead > xxx	Yellow	STx > Elevation limit. ST segment is elevated	ST/AR Arrhythmia
* ST lead < xxx	Yellow	STx < Depression limit. ST segment is depressed.	ST/AR Arrhythmia
* SVT	Yellow	Supra Ventricular Tachycardia. SVT for > 15 seconds	ST/AR Enhanced Arrhythmia

Technical Alarms (INOPs)

Physiologic (Patient) Alarms

Alarm Text	Priority	Condition	Source
* VENT BIGEMINY	Yellow	Ventricular Bigeminy. Predominant Bigeminy rhythm present.	ST/AR Enhanced Arrhythmia
* VENT RHYTHM	Yellow	Ventricular Rhythm. Ventricular rhythm present.	ST/AR Enhanced Arrhythmia
* VENT TRIGEMINY	Yellow	Ventricular Trigeminy. Predominant Trigeminy rhythm present.	ST/AR Enhanced Arrhythmia
Notes: xxx = limit that was exceeded; yyy = current value. * NBP alarms are processed independently at the Information Center. The alarm delay from TeleMon to the Information Center is not more than 10 seconds.			

Technical Alarms (INOPs)

Technical Alarms, or INOPs, are sourced at the transceiver, the ST/AR algorithm running at the Information Center, or TeleMon Companion Monitor, and identify inoperative conditions (that is conditions where the system cannot measure or detect alarm conditions reliably). There are three levels of Technical Alarms:

- **Severe** - Monitoring and alarms disabled. Audible tone at the Information Center. Must be acknowledged by a clinician.
- **Hard** - Monitoring and alarms are disabled. Audible tone at the Information Center.
- **Soft** - Monitoring and alarms remain active. No audible tones are generated.

Technical Alarms (Inoperative Conditions) (in alphabetic order)

Alarm Text	Priority	Condition	What to do
BATTERY LOW	Soft	Power is low.	Replace batteries promptly to avoid transceiver shutdown and cessation of monitoring.
CANNOT ANALYZE ECG	Hard	Arrhythmia algorithm cannot reliably analyze the ECG data on any monitored leads.	Assess the lead selections, initiate relearn, and validate analyzed rhythm.
CANNOT ANALYZE ST	Soft	ST algorithm cannot reliably generate any valid ST values on any monitored lead.	Review the ECG signal quality and correct if necessary. Reposition the Is and J points.
CHARGE MON BAT	Hard	TeleMon battery charge is less than or equal to 25%.	Connect TeleMon to AC power and charge battery, or insert battery with charge greater than 25%.
CUFF NOT DEFLATED	Severe	Cuff pressure is greater than a specified safety limit for a period of time.	Remove cuff from patient and disconnect from tubing. Gently expel any air. If water in cuff, replace cuff. Reconnect, and reapply cuff to patient. <i>Note</i> —If the alarms are suspended, this INOP will unsuspends them at the Information Center and TeleMon. To clear the INOP message, initiate a new NBP measurement.

Technical Alarms (INOPs)

Technical Alarms (Inoperative Conditions) (in alphabetic order)

Alarm Text	Priority	Condition	What to do
ECG EQUIPMENT MALF	Hard	Failure of the ECG equipment or failure to calibrate ECG.	Replace the transceiver or calibrate ECG with Service Tool.
ECG LEADS OFF	Hard	Multiple leads off	Reattach ECG leads to patient.
<electrode> LEAD OFF	Hard	Primary lead is off. <i>Note</i> —If primary lead is MCL, lead will be identified as V in INOP text.	Reattach ECG lead to patient.
<electrode> LEAD OFF	Soft	Non-primary lead is off.	Reattach ECG lead to patient.
INVALID LEADSET	Hard	Bad lead selection switches in the transceiver	Replace transceiver case. Use supported leadset. Contact Service.
NO SIGNAL	Hard	Patient is out of range, radio board has failed, ICN connection failure, or no batteries in transmitter.	Make sure that the transceiver is in own care-group range and has good batteries. Replace the transceiver if Power On Self Test fails, and notify Service Provider.
REPLACE BATTERY	Hard, Latched Message remains until acknowledged by clinician.	Dead battery. No monitoring is occurring.	Replace batteries.

Technical Alarms (Inoperative Conditions) (in alphabetic order)

Alarm Text	Priority	Condition	What to do
SOME ECG ALRMS OFF	Soft	Some yellow arrhythmia alarms have been turned off for this patient.	For information only.
SpO ₂ T EQUIP MALF	Hard	Malfunction in the SpO ₂ equipment	SpO ₂ board needs to be replaced. Call Service.
SpO ₂ T ERRATIC	Hard	Erratic SpO ₂ measurements, often due to a faulty sensor or invalid SpO ₂ measurements, or incorrect transducer position	Repeat measurement, reposition sensor on patient, or finally, replace sensor.
SpO ₂ T EXTD UPDATE Numeric is replaced by a -?-.	Soft	The update period of displayed values is extended due to an NBP measurement on the same limb or an excessively noisy signal.	If NBP is not active, check the sensor placement. Reposition the sensor on patient, or replace sensor.
SpO ₂ T INTERFERENCE	Hard	Level of ambient light or level of electrical interference are so high that the SpO ₂ sensor cannot measure SpO ₂ and pulse rate.	Reduce ambient light to sensor or electrical noise sources.
SpO ₂ T LOW PERFUSION	Soft	Accuracy may be reduced due to low perfusion. Data displayed with ?. Warm the site.	Increase perfusion. Change sensor site. Avoid site distal to BP cuff or intra-arterial line.
SpO ₂ T NO SENSOR	Hard	No sensor attached to SpO ₂ device	Attach SpO ₂ sensor.

Technical Alarms (INOPs)

Technical Alarms (Inoperative Conditions) (in alphabetic order)

Alarm Text	Priority	Condition	What to do
SpO ₂ T NOISY SIGNAL	Hard	Excessive patient movements or electrical interference are causing irregular pulse patterns	Reduce movement or electrical noise sources.
SpO ₂ T NON-PULSATILE	Hard	Pulse is too weak or not detectable	Check connection to patient. Change sensor site. Avoid site distal to BP cuff or intra-arterial line.
SpO ₂ T SENSOR MALF	Hard	Malfunction of the SpO ₂ sensor/adaptor-cable	Replace sensor.
TELEMETRY STANDBY	Soft	Information Center standby mode timer is active, or patient was not returned to telemetry coverage area. There is no data from bed.	Cancelled when patient is removed from Standby.
TRANSMITTER MALF	Hard	Transceiver malfunction	Replace and notify Service Provider.
TRANSMITTER OFF	Hard	RF shut off after 10 minutes of leads off	Reattach ECG leads to patient.
WEAK SIGNAL	Soft	Patient is at outer range of the radio coverage area. Telemetry pack is receiving a weak signal with high data loss from the AP.	Return patient to the radio coverage area. If patient is in close proximity to AP, replace telemetry pack. If condition exists for multiple devices in a specific area, the AP in that area is suspect. Contact Service.

3

ECG Monitoring

This chapter covers the specifics of ECG measurement. It includes the following sections:

- ECG Safety Information 3-2
- Measuring ECG 3-3
- Positioning ECG Electrodes 3-8
- Connecting the ECG Cable. 3-19
- Verifying Electrode Connections 3-22
- Monitoring during Leads Off 3-23
- Optimizing ECG Measurement Performance. 3-25

ECG Safety Information

Warning

For ALL Patients:

Always confirm Information Center observations with clinical observation of the patient before administering interventions.

Every lead must be secured to an electrode on the patient.

Conductive parts of electrodes must not contact earth or other conductive parts.

Philips recommends that you change the lead label only to reflect the physical placement of electrodes. This will ensure a match between the monitored lead and the label, and prevent any possible confusion.

When switching from EASI to standard monitoring, there is a loss of data for 30 seconds.

For PACED Patients:

The output power of the transceiver and other sources of radio frequency energy, when used in the proximity of a pacemaker, can be sufficient to interfere with pacemaker performance. Due to the shielding effects of the body, internal pacemakers are somewhat less vulnerable than external pacemakers. However, caution should be exercised when monitoring any paced patient.

In order to minimize the possibility of interference, position electrodes, electrode wires, and the transceiver as far away from the pacemaker as possible.

Consult the pacemaker manufacturer for information on the RF susceptibility of their products and the use of their products with the Philips IntelliVue Telemetry System. See the *IntelliVue Information Center Instructions for Use* for additional information on monitoring paced patients.

Measuring ECG

The electrocardiogram (ECG) measures the electrical activity of the heart and displays it on the Information Center as a waveform and a numeric.

There is no cardiotech within the transceiver; cardiotech analysis resides in the arrhythmia algorithm at the Information Center. Arrhythmia analysis is always turned on for telemetry patients. Arrhythmia analysis is either basic or enhanced, depending on the product configuration.

EASI ECG

EASI[®] derived 12-lead ECGs and their measurements are approximations to conventional 12-lead ECGs. As the 12-lead ECG derived with EASI is not exactly identical to the 12-lead conventional ECG obtained from an electrocardiograph, it should not be used for diagnostic interpretations.

ECG Leadsets

The IntelliVue Transceiver supports 3-, 5-, and 6-wire leadsets. It detects the inserted leadset type and automatically determines the ECG measurement and transmitted leads. The Leadset Insertion Guide on the device will assist you in ensuring the correct measurement during transceiver usage (see “Connecting the ECG Cable” on page 3-19). The 5-wire leadset can be used for either standard or EASI electrode configurations. The leadsets are compatible with the 5- and 3-wire leadsets used with the IntelliVue family of monitors and with M2601B transmitters.

The electrode placements for the illustrations in this chapter use the AAMI labels and colors and are summarized in the following table.

Leadset	Electrode Color (AAMI)	Electrode Location
3-wire	Black White Red	LA RA LL

Measuring ECG

Leadset	Electrode Color (AAMI)	Electrode Location
5-wire (Standard mode)	Black White Red Green Brown	LA RA LL RL V
5-wire (EASI mode)	Black White Red Green Brown	S I A RL E
6-wire	Black White Red Brown Green Brown/White	LA RA LL Va RL Vb

ECG Leads Monitored

Depending on the leadset connected to the transceiver, a different set of viewable leads are available at the Information Center. The transceiver can

source up to four raw ECG waves. The transceiver automatically recognizes the leadset connected.

If you are using ...	these leads can be selected at the Information Center
3-wire	<p>I, II, III</p> <p>If lead selection is enabled, sourced waves are received as:</p> <ul style="list-style-type: none"> • Channel 1 - I • Channel 2 = II • Channel 3 = III <p>If lead selection is disabled, the sourced wave is II.</p> <p>Default is II.</p>
5-wire (Standard mode)	<p>I, II, III, aVR, aVL, aVF, MCL and V</p> <p>Sourced waves are received as:</p> <ul style="list-style-type: none"> • Channel 1 - I • Channel 2 = II • Channel 3 = III <p>Defaults are II, V, III.</p>
5-wire (EASI mode)	<p>I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6</p> <p>In EASI mode, the sourced waves are received as:</p> <ul style="list-style-type: none"> • Channel 1 = Vector 1 (A-I) • Channel 2 = Vector 2 (A-S) • Channel 3 = Vector 3 (E-S) <p><i>Note</i>—Arrhythmia monitoring is performed only on the primary and secondary leads selected at the Information Center, although you can view and perform ST analysis on all 12 EASI derived leads.</p>

Measuring ECG

If you are using ...	these leads can be selected at the Information Center
<p>6-wire (not supported in TeleMon)</p>	<p>I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6, V7, V8, V9, V_{3R}, V_{4R}, V_{5R}.</p> <p>Sourced waves are received as:</p> <ul style="list-style-type: none"> • Channel 1 = II • Channel 2 = III • Channel 3 = Va • Channel 4 = Vb <p>The two chest leads, Va and Vb, can be placed on the patient in any of the V lead positions (V1 through V9, V3R, V4R, V5R). Lead assignment is available at the Information Center. When unassigned, the chest leads use the defaults.</p> <p>Defaults are II, III, Va=V2, Vb=V5.</p> <p><i>Note</i>—When display of the pleth wave is enabled at the Information Center, the second chest lead (Vb) is not available for monitoring due to bandwidth limit. That is, the lead label assigned to Vb cannot be selected for Va even though Vb does not appear to be used.</p>

Reconstructed Leads

Reconstruction of leads from the sourced wave is defined by the calculations in the following table. EASI reconstructed leads are a linear combination of all three raw EASI leads. Default labels/leads are shown in bold text.

ECG Lead			Clinical Calculations in terms of electrodes
3-Lead	5-Lead Standard	6-Lead	
I	I	I	LA-RA

ECG Lead			Clinical Calculations in terms of electrodes
3-Lead	5-Lead Standard	6-Lead	
II	II	II	LL-RA
III	III	III	LL-LA
-	MCL	-	Va-LA, C=Va (see Note)
-	aVR	aVR	RA-(LA+LL)/2
-	aVL	aVL	LA-(RA+LL)/2
-	aVF	aVF	LL-(LA+RA)/2
-	V		C-(RA+LA+LL)/3, where C=V
		Va	C-(RA+LA+LL)/3, where Va= V2 position
		Vb	Vb-(RA+LA+LL)/3, where Vb = V5

Positioning ECG Electrodes

Warning

Do not mix and match electrodes of different types. In particular, do not use electrodes of dissimilar metals. This helps ensure optimal signal quality.

Warning

When you are connecting the electrodes or the patient cable, make sure that the connectors never come into contact with other conductive parts, or with earth. In particular, make sure that all of the ECG electrodes are attached to the patient, to prevent them from contacting conductive parts or earth.

Warning

Non-manufacturer supplied accessories and supplies can corrupt the performance of the equipment. Use only AAMI EC-12 compliant electrodes with this device. Use of electrodes that are non-compliant may provide erroneous results.

Caution

To protect the transceiver from damage during defibrillation, to ensure accurate ECG information, and to provide protection against signal noise and other interference, use only ECG electrodes and cables specified by Philips.

To make it possible to compare measured ECG signals, the electrodes (or leadsets) are placed in standardized positions, forming so-called "leads". To obtain ECG signals optimized for use in diagnosis and patient management in different care environments, different leadsets in varying lead placements can be used. You can use either standard lead placements or EASI lead placements with the transceiver.

Positioning ECG Electrodes

When placing electrodes on the patient, choose a flat, non-muscular site where the signal will not be impacted by either movement or bones. Correct lead placement is always important for accurate diagnosis. Especially in the precordial leads, which are close the heart, QRS morphology can be greatly altered if an electrode if moved away from its correct location.

In addition to correct positioning of the electrodes, optimal skin preparation prior to electrode placement will help ensure a clear signal for diagnosis.

Step	Action
1	<p>Prepare the patient's skin. Good electrode-to-skin contact is important for a good ECG signal, as the skin is a poor conductor of electricity.</p> <ul style="list-style-type: none">• Select sites with intact skin, without impairment of any kind.• Clip or shave hair from the site as necessary.• Wash site with soap and water, leaving no soap residue. <i>Note--Philips does not recommend using ether or pure alcohol, because they dry the skin and increase the resistance.</i>• Dry thoroughly.• Use ECG skin preparation paper (abrasive) to remove dead skin cells and to improve the conductivity of the electrode site.

Positioning ECG Electrodes

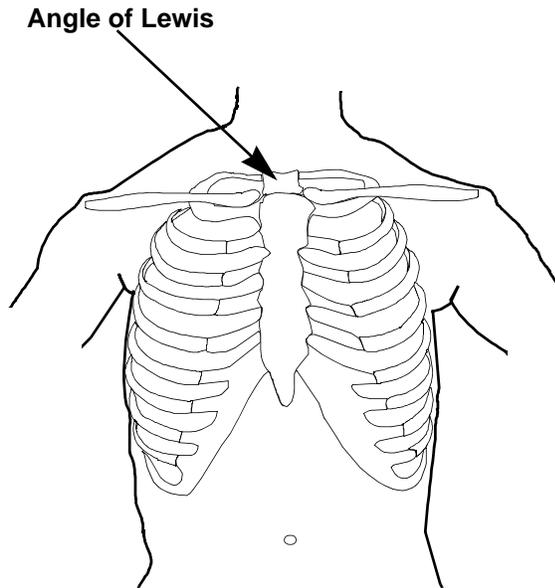
Step	Action
2	<p>Check electrodes for moist gel, and attach to the clips. If you are not using pre-gelled electrodes, apply electrode gel to the electrodes before placement.</p> <p><i>Note</i>—Gel must be moist to provide a good signal.</p>
3	<p>Place the electrodes on the patient according to the lead placement you have chosen (see Electrode Placement following). Place the edge down, then "roll down" the rest of the pad. Press firmly around the adhesive edge toward the center.</p> <p><i>Note</i>—When placing electrodes, choose a flat, non-muscular site where the signal will not be interfered with by either movement or bones. Correct lead placement is always important for accurate measurement, especially in the precordial leads, which are close to the heart. QRS morphology can be greatly altered if an electrode is moved away from its correct location.</p>

Electrode Placement

Diagrams for 5-lead standard and EASI electrode placement are located on the back of the transceiver. Additional lead placement information is available in the Online Help in the IntelliVue Information Center.

Philips recommends that electrodes be changed every 24 hours.

**Locating the
Fourth
Intercostal
Space**

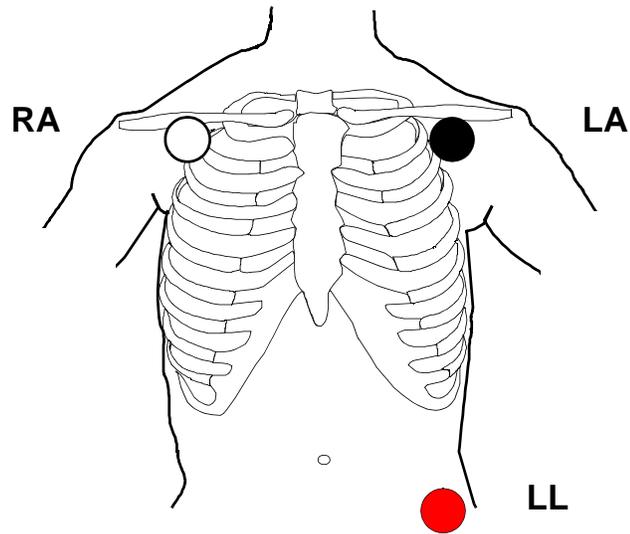


For accurate chest electrode placement and measurement, it is important to locate the fourth intercostal space. This can be done using the Angle of Lewis.

1. Locate the second intercostal space by first palpating the Angle of Lewis (the bony protuberance where the body of the sternum joins the manubrium). This rise in the sternum is where the second rib is attached, and the space just below this is the second intercostal space.
2. Palpate and count down the chest until you locate the fourth intercostal space.

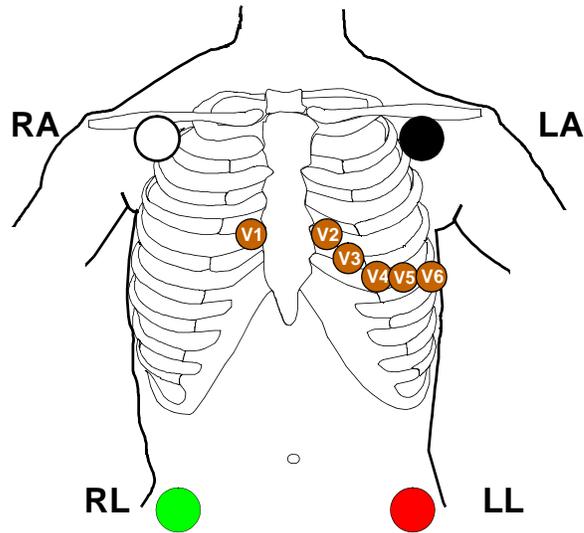
Positioning ECG Electrodes

3-Lead Placement



Lead	Placement
RA	directly below the clavicle and near the right shoulder
LA	directly below the clavicle and near the left shoulder
LL	on the left lower abdomen

5-Lead Placement (Standard Mode)



Lead	Placement
RA	directly below the clavicle and near the right shoulder
LA	directly below the clavicle and near the left shoulder
LL	on the left lower abdomen
RL	on the right lower abdomen
V	on the chest, the position depends on your required lead selection. The default position is V2.
V1	on the fourth intercostal space at the right sternal border

Positioning ECG Electrodes

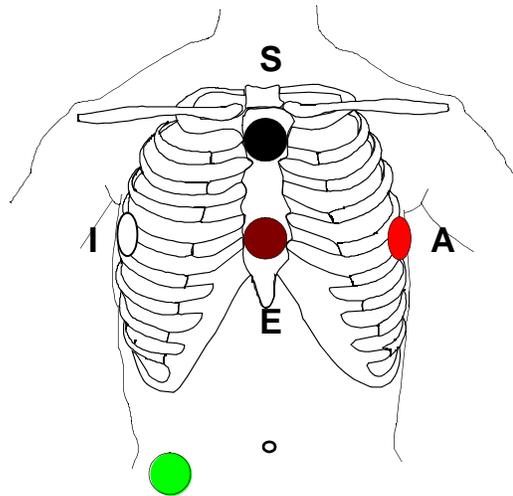
Lead	Placement
V2	on the fourth intercostal space at the left sternal border
V3	midway between the V2 and V4 electrode positions
V4	on the fifth intercostal space at the left midclavicular line
V5	on the left anterior axillary line, horizontal with the V4 electrode position
V6	on the left anterior axillary line, horizontal with the V4 electrode position

**5-Lead
Placement
(EASI Mode)**

Warning

EASI derived 12-lead ECGs and their measurements are approximations to conventional 12-lead ECGs. As the 12-lead ECG derived with EASI is not exactly identical to the 12-lead conventional ECG obtained from an electrocardiograph, it should not be used for diagnostic interpretations.

EASI lead placement is supported for adult patients only



Lead	Corresponds to Standard Lead	Placement
E	V	on the lower sternum at the level of the fifth intercostal space
A	LL	on the left midaxillary line at the same level as the E electrode

Positioning ECG Electrodes

Lead	Corresponds to Standard Lead	Placement
S	LA	on the upper sternum
I	RA	on the right midaxillary line at the same level as the E electrode
N	Reference	can be anywhere, usually below the sixth rib on the right hip

Note—Make sure that the D and E electrodes line up vertically on the sternum, and that the I, E and A electrodes align horizontally.

6-Lead Placement

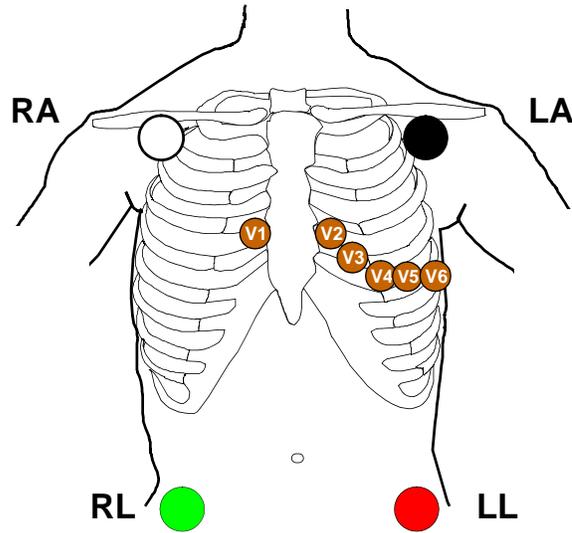
A 6-lead placement uses the same four limb leads as 5-lead standard placement, and two precordial leads - referred to at the Information Center as Va and Vb.

The default position of Va - the brown lead - is at the V2 position.

The default position for Vb - the brown/white lead - is at the V5 position.

Your unit may use other precordial leads for Va and Vb. In that situation, you need to assign those new positions in the Patient Window at the Information Center. The Va and Vb default positions can be changed in the configuration at the Information Center on a per patient basis.

Positioning ECG Electrodes



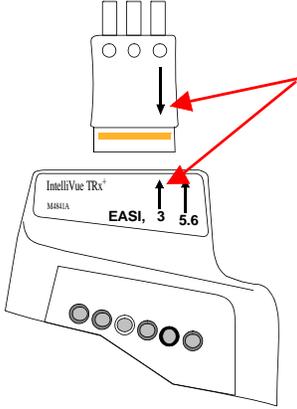
Lead	Placement
RA	directly below the clavicle and near the right shoulder
LA	directly below the clavicle and near the left shoulder
RL	on the right lower abdomen
LL	on the left lower abdomen
Va	on the chest, the position depends on your required lead selection. The Philips default position is V2. For other positions, relabel the lead at the Information Center.

Positioning ECG Electrodes

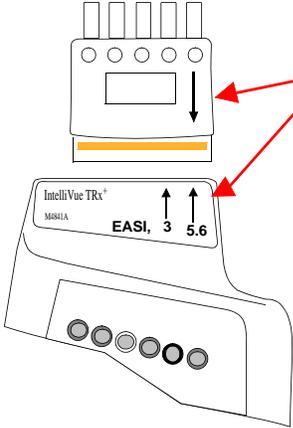
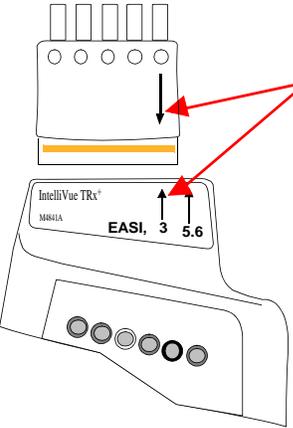
Lead	Placement
Vb	on the chest, the position depends on your required lead selection. The Philips default position is V5. For other positions, relabel the lead at the Information Center.
V1	on the fourth intercostal space at the right sternal border
V2	on the fourth intercostal space at the left sternal border
V3	midway between the V2 and V4 electrode positions
V4	on the fifth intercostal space at the left midclavicular line
V5	on the left anterior axillary line, horizontal with the V4 electrode position
V6	on the left anterior axillary line, horizontal with the V4 electrode position

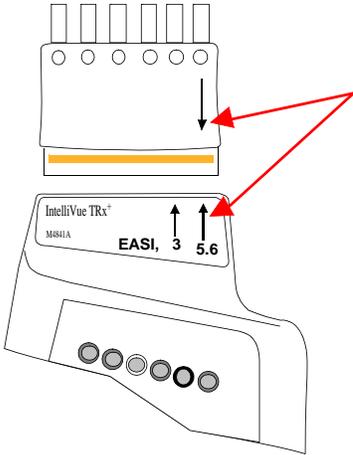
Connecting the ECG Cable

Note—Your transceiver may have alignment guides to assist you in leadset insertion.

Step	Action
1	<p>Match the arrow on the ECG cable with the arrow on the Lead Insertion Guide according to the lead type you have chosen, and insert the ECG cable into the transceiver.</p> <p><i>Important</i>—Make sure that the cable is pushed <i>completely</i> into the transceiver. When correctly inserted, the orange line at the base of the cable is not visible.</p>
	<p>3-wire</p>  <p>Match the arrow on the cable with the left arrow (labeled EASI, 3) on the Leadset Insertion Guide.</p> <p><i>Note</i>—Leadset is keyed for only one insertion position.</p>

Connecting the ECG Cable

Step	Action
	<p data-bbox="586 485 789 512">5-wire Standard</p>  <p data-bbox="956 533 1321 653">Match the arrow on the cable with the right arrow (labeled 5, 6) on the Leadset Insertion Guide.</p> <p data-bbox="586 995 737 1022">5-wire EASI</p>  <p data-bbox="956 1037 1308 1157">Match the arrow on the cable with the left arrow (labeled EASI, 3) on the Leadset Insertion Guide.</p> <p data-bbox="586 1514 1317 1633"><i>Note</i>—If you are using a 5-wire leadset in both Standard and EASI modes, insert the protective plug into the open lead port with the wide lip facing the leads. Then, press down firmly so that the plug is securely under the leadset and the orange line is not visible.</p>

Step	Action
	<p>6-wire</p>  <p>Match the arrow on the cable with the right arrow (labeled 5,6) on the Leadset Insertion Guide.</p>
2	<p>Check that the correct Electrode Indicators are lit for the leadset you are using, and that the EASI indicator light is illuminated appropriately. See “Verifying Electrode Connections” on page 3-22.</p> <ul style="list-style-type: none"> • When using 5-lead standard, the EASI indicator does not illuminate. • When using EASI, the EASI indicator illuminates momentarily.
3	<p>For 3-lead, select the lead label(s) at the Patient Window.</p>

Cable Disconnection

When disconnecting the leadset from the transceiver, grasp the leadset firmly and pull free. Do not pull on the lead wires.

Verifying Electrode Connections

The electrode indicators enable you to verify that the leads are available for the desired monitoring. Each electrode is color-coded. Pressing and holding the Check button enables you to view the leadset status. During routine use of the transceiver for monitoring, all lead indicators are off.

To verify electrode connections, use the following procedure:

Step	Action
1	Press and hold the Check button for 2 seconds
2	Expected Response: <ul style="list-style-type: none">• If 3-wire cable is attached: Red, White and Black indicators illuminate, then all turn off.• If 5-wire cable in Standard mode is attached: Red, White, Black, Green & Brown indicators illuminate, then all turn off.• If 5-wire cable in EASI mode is attached: Red, White, Black, Green & Brown indicators illuminate, then all turn off. The EASI indicator also illuminates briefly.• If 6-wire cable is attached: Red, White, Black, Green, Solid Brown and Brown/White indicators illuminate, then all turn off.• If no leadset is attached: all indicators are off.
3	Unexpected Response: <p>Any other response indicates a problem with the transceiver. Check the leadset connection and/or use a new leadset. If the problem is not corrected, contact your Service Provider.</p>

During routine monitoring, the electrode indicators also notify you if one or more leads are not functioning. When a LEADS OFF condition occurs, the transceiver automatically illuminates the indicator corresponding to the missing lead.

Monitoring during Leads Off

ECG Fallback and Extended monitoring states are supported for the transceiver when the primary and/or secondary leads are in a Leads Off INOP condition. Both these states are entered into after 10 seconds of Leads Off in an attempt to maintain monitoring and arrhythmia analysis.

ECG Fallback

ECG Fallback occurs when the primary lead is in Leads Off for 10 seconds and a secondary lead is available. ECG Fallback must be configured on by your Service Provider.

Multilead Analysis

If there is a LEADS OFF technical alarm in the primary lead for > 10 seconds, the active secondary lead becomes the primary lead. The arrhythmia algorithm switches the leads on the display, but relearn does not occur. When the Leads Off condition is corrected, the leads are switched back to their original state.

Single Lead Analysis

For single lead analysis, if there are two leads available, the secondary lead is made the primary lead until the Leads Off condition is corrected. The arrhythmia algorithm performs a relearn using the available lead.

Fallback for EASI

If one of the derived EASI leads is in a technical alarm condition, a flat line is displayed. After 10 seconds, the directly acquired EASI AI, AS, or ES lead, depending on which is available, is displayed with the label "ECG". Arrhythmia relearn is performed with transition to or from EASI Fallback monitoring using the available lead(s).

Monitoring during Leads Off

Extended Monitoring

Extended monitoring occurs when *both* the primary and secondary leads are in Leads Off for 10 seconds and another lead is available. It becomes the primary lead and the arrhythmia algorithm performs a relearn.

Extended Monitoring applies if:

- Telemetry is configured for Extended Monitoring ON.
- The lead set provides more than two leads (e.g., when using a 5-wire leadset). The leadset must provide more than two leads, and Extended monitoring must be configured on by your Service Provider.

Relearning

Whenever there is a Leads Off condition, the arrhythmia algorithm performs a Relearn, using the available leads.

Warning

Since Relearn happens automatically, if learning takes place during ventricular rhythm, the ectopics can be incorrectly learned as the normal QRS complex. This can result in missed detection of subsequent events of V-Tach and V-Fib. For this reason, you should:

- 1. Respond promptly to any technical alarm.**
 - 2. Ensure that the arrhythmia algorithm is labeling beats correctly.**
-
-

Using EASI Leads to Troubleshoot

If there is artifact in the ECG waves or a CANNOT ANALYZE ECG technical alarm condition is in effect, you can use the three EASI leads to troubleshoot:

1. Click **12-Lead ECG** on the Patient Window, then on **3 EASI Leads**.
2. The three directly acquired EASI leads will be displayed so that you can determine which electrodes are causing the problem and need to be replaced.

Optimizing ECG Measurement Performance

While telemetry monitoring offers many advantages, it can be a challenge. The reliability and quality of the signal transmission through the air and hospital walls is governed by a number of variables which can be difficult to control. A telemetry system cannot be as dependable as a hardwired bedside monitor that transmits its signal through a wire.

The effect of interference on the Philips IntelliVue Telemetry System ranges from a momentary loss of ECG to complete inoperability, depending on the situation. The strength, frequency, and proximity of the source of interference to the transceiver devices or the access point system are factors that determine the degree of severity. In cases where the source of interference is known - for example, cellular phones, magnetic equipment such as MRI, other radio or motorized equipment - removing or moving away from the source of interference will increase the equipment's dependability.

Warning

Philips IntelliVue Telemetry System should not be used for primary monitoring in applications where the momentary loss of the ECG is unacceptable.

In this section, we'll investigate some of the problems affecting ECG signal clarity and when possible, show you how you can greatly enhance performance.

Important—Philips IntelliVue Telemetry System also emits radio frequencies that can affect the operation of other devices. Contact the manufacturer of other equipment for possible susceptibility to these frequencies.

The Telemetry Signal

The transceiver worn by the patient acquires the patient's physiological data, amplifies and digitizes it, detects pace pulses and broadcasts this information via radio waves to the Philips IntelliVue Telemetry System. Since the signal passes through the air, it is susceptible to interference from many sources.

Trouble- shooting Signal Disturbances

Dropouts

Because Philips IntelliVue Telemetry System is a wireless system, under certain conditions RF (Radio Frequency) “dropouts” can occur. Dropouts result from a weak signal or RF interference. There will be signal drops to the bottom of channel for a minimum of 200 ms to indicate to the clinical user that it is a non-physiological event. If dropouts are frequent enough to affect the heart rate count, the CANNOT ANALYZE ECG or CANNOT ANALYZE ST technical alarm occurs. The following recording strip is an example of dropouts.



If frequent dropouts are occurring, the following section describes some steps you can take to improve performance.

Signal Strength

The Philips IntelliVue Telemetry System is custom designed for your unit, so reliable signal reception is only possible where there are receiving access points. When the signal is too low, the following technical alarms occur:

- CANNOT ANALYZE ECG
- CANNOT ANALYZE ST
- WEAK SIGNAL
- NO SIGNAL

To correct, first check the location of the patient. If the patient is not in the coverage area, do one of the following.

- Return the patient to the specified coverage area.
- Put telemetry in Standby Mode. See “Standby Mode” on page 2-5.
- If the patient is in the coverage area and is stationary, try moving the location of the transceiver from its original location by about 15 cm (6 inches).

Radio Frequency Interference

Radio frequency (RF) interference is caused by anything that intrudes into the transmitted electrical signal, such as paging transmitters. You are probably familiar with electrical interference in our homes and cars when it causes signal loss or static with cell phones. These same types of interference can occur with the transmitted telemetry signal. Even though the Philips IntelliVue Telemetry System is designed to resist these effects, interference can occasionally be seen in the form of “dropouts”. To improve performance, the source of the interference must be identified and eliminated.

Muscle and Movement Artifact

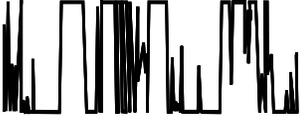
Muscle and movement artifact differ from radio frequency interference since you can prevent much of the occurrence. Noise on the ECG signal can be caused by many sources, such as interference from other electrical equipment, muscle artifact and respiratory variation. It is up to the clinician to use certain techniques to minimize these types of noise.

Use the following table to help you troubleshoot the most common sources of ECG noise.

Troubleshooting Common Causes of ECG Noise

Problem	Cause	Remedy
60-Cycle (AC) Interference 	Poor electrode placement. Possible non-grounded instrument near patient	Apply fresh electrodes after recommended skin preparation. Disconnect electrical appliances near patient (one at a time) by pulling wall plugs, to determine faulty grounding. Have engineering check grounding.
Muscle Artifact 	Tense, uncomfortable patient. Poor electrode placement. Tremors. Diaphoresis	Make sure patient is comfortable. Check that electrodes are applied on flat non-muscular areas of the torso; apply fresh electrodes after recommended skin preparation if necessary (see “Positioning ECG Electrodes” on page 3-8).

Troubleshooting Common Causes of ECG Noise

Problem	Cause	Remedy
<p>Irregular Baseline</p> 	<p>Poor electrical contact. Respiratory interference. Faulty electrodes. Dry electrodes.</p>	<p>Apply fresh electrodes after recommended skin preparation if necessary (see “Positioning ECG Electrodes” on page 3-8). Move electrodes away from areas with greatest movement during respiration.</p>
<p>Baseline Wander</p> 	<p>Movement of patient. Improperly applied electrodes. Respiratory interference.</p>	<p>Make sure patient is comfortable. Apply fresh electrodes after recommended skin preparation if necessary (see “Positioning ECG Electrodes” on page 3-8). Check that patient cable is not pulling electrodes. Move electrodes away from areas with greatest movement during respiration.</p>
<p>Poor Electrode Contact</p> 	<p>Loose electrodes. Defective cables. Leadset not firmly connected.</p>	<p>Apply fresh electrodes after recommended skin preparation if necessary (see “Positioning ECG Electrodes” on page 3-8). Replace cables.</p>

4

ST/AR Arrhythmia & ST Segment Monitoring

This chapter describes the ST/AR algorithms used for telemetry at the Philips Information Center. It includes the following sections:

- ST/AR Arrhythmia Algorithm 4-2
- ST/AR provides Heart Rate and PVC Rate numerics and alarm detection for the conditions listed in the following table. There are two detection levels: Basic and Enhanced. Enhanced includes the Basic alarms. 4-4
- The Measurement 4-6
- Adjusting ST Measurement Points 4-9
- Establishing ST Reference Beats (Baseline) 4-11
- ST Alarm Settings. 4-11
- ST Alarm Settings. 4-11

ST/AR Arrhythmia Algorithm

Safety Information

Warning

FOR ALL PATIENTS

During complete heart block or pacemaker failure (to pace or capture), tall P-waves (greater than 1/5 of the average R-wave height) can be erroneously counted by the arrhythmia algorithm, resulting in missed detection of cardiac arrest.

Learning/Relearning

- **Learning:** If you initiate learning during ventricular rhythm, the ectopics can be incorrectly learned as the normal QRS complex. This can result in missed detection of subsequent events of V-Tach and V-Fib.

- **Relearning:** When using EASI ECG monitoring, Relearn happens automatically when there is a LEADS OFF technical alarm. If learning takes place during ventricular rhythm, the ectopics can be incorrectly learned as the normal QRS complex. This can result in missed detection of subsequent events of V-Tach and V-Fib. Be sure to check the beat labels and initiate a relearn to correct.

1. Respond to the technical alarm [for example, reconnect the electrode(s)].
 2. Ensure that the arrhythmia algorithm is labeling beats correctly.
-
-

Warning

FOR PACED PATIENTS

It is possible that pacemaker pulses will not be detected when the ECG analog output of a defibrillator or telemetry unit is plugged into a bedside monitor. This can result in the arrhythmia algorithm's failure to detect pacemaker non-capture or asystole.

Some pace pulses can be difficult to reject. When this happens, the pulses are counted as a QRS complex, and could result in an incorrect HR and failure to detect cardiac arrest or some arrhythmias. Keep pacemaker patients under close observation.

-- During complete heart block or pacemaker failure (to pace or capture), tall P-waves (greater than 1/5 of the average R-wave height) can be erroneously counted by the arrhythmia algorithm, resulting in missed detection of cardiac arrest.

-- When arrhythmia monitoring paced patients who exhibit only intrinsic rhythm, the monitor can erroneously count pace pulses as QRS complexes when the algorithm first encounters them, resulting in missed detection of cardiac arrest.

For patients who exhibit intrinsic rhythm only, the risk of missing cardiac arrest can be reduced by monitoring these patients with the low heart rate limit at or slightly above the basic/demand pacemaker rate. A low heart rate alarm alarms you when the patient begins pacing. Proper detection and classification of the paced rhythm can then be determined.

-- When an external pacemaker is being used on a patient, arrhythmia monitoring is severely compromised due to the high energy level in the pacer pulse. This can result in the arrhythmia algorithm's failure to detect pacemaker non-capture or asystole.

**ST/AR
Arrhythmia
Analysis**

For information on arrhythmia detection, refer to the following documentation:

- *ST/AR Algorithm - Arrhythmia Monitoring* Application Note (4522 981)

ST/AR Arrhythmia Algorithm

93051)

- IntelliVue Information Center Instructions for Use and Online Help

The intended use of the ST/AR basic arrhythmia analysis algorithm is to monitor the patient's ECG for heart rate and ventricular arrhythmias and to produce events/alarms simultaneously for one or more ECG leads. The arrhythmia algorithm is effective when monitoring both paced and non-paced patients in a clinical environment.

IntelliVue Telemetry does not have a dedicated cardioteach. Instead, the arrhythmia cardioteach at the Information Center is used. Therefore, the ST/AR Arrhythmia algorithm is always on for all IntelliVue Telemetry patients, and cannot be turned off.

ST/AR provides Heart Rate and PVC Rate numerics and alarm detection for the conditions listed in the following table. There are two detection levels: Basic and Enhanced. Enhanced includes the Basic alarms.

Basic & Enhanced Arrhythmia Detection

Basic Arrhythmia Detection	Enhanced Arrhythmia Detection	
Asystole	Tachy yyy > xxx	Vent Bigeminy
Vent Fib/Tach	Brady yyy < xxx	Vent Trigeminy
V tach	Non-Sustain VT	Multiform PVCs
Extreme Brady	Vent Rhythm	HR yyy > xxx
Extreme Tachy	Run PVCs	HR yyy < xxx
High HR	Pair PVCs	Irregular HR
Low HR	Pause	
PVCs > 30/min	Missed Beat	
Pacer Not Capturing	SVT	
Pacer Not Pacing	R-on-T PVCs	

ST/AR Arrhythmia Algorithm

Beat classification determined by the ST/AR algorithm is shown on the primary delayed wave in the Arrhythmia Analysis window at the Information Center. To access this window, select Arrhythmia Analysis from the Patient Window.

The annotation requires clinical validation of the analyzed heart rhythm. If the analysis is inaccurate, perform a relearn of the rhythm.

Annotation	Beat Classification	Color
A	Artifact	Blue
I	Inoperative	Red
L	Learning	Red
M	Missed Beat	Red
N	Normal	Blue
P	Paced	Blue
S	Supraventricular Premature	Blue
V	Ventricular Premature	Red
?	Questionable	Red
‘	Pacer Mark	Blue

When monitoring is initiated, when the Wave 1 lead is changed, or if Relearn is selected, a question mark (?) is displayed next to HR and the annotation “L” appears on the annotated wave until the HR is calculated and the rhythm is learned.

ST/AR ST Segment Algorithm

Warning

This device provides ST level change information; the clinical significance of the ST level change information should be determined by a physician.

The ST/AR ST algorithm at the Information Center (not available for M3153A) monitors ST segment elevation or depression for each available telemetry ECG lead and produces events/alarms simultaneously. ST values update with every measurement period and enunciate, depending upon the severity of the change, events and alarms as they are detected.

The ST/AR ST algorithm is approved for use only with non-paced and atrially-paced adult telemetry-monitored patients. With EASI monitoring, ST analysis is performed on up to 12 leads, and an additional value of ST index is calculated and displayed (see “EASI ST Analysis” on page 4-8). Assessment of EASI-derived 12-lead ST measurement is recommended for adult patients that meet the following parameters:

- Ages: 33-82 years
- Heights: 147 to 185 cm (58 to 73 in)
- Weights: 53 to 118 kg (117 to 261 lbs)
- Height to Weight Ratios: 1.41 to 2.99 cm/kg (0.25 to 0.54 in/lb)

All ST analysis and ST alarms for telemetry patients are performed by the Information Center.

For additional information on ST monitoring, refer to the following documentation:

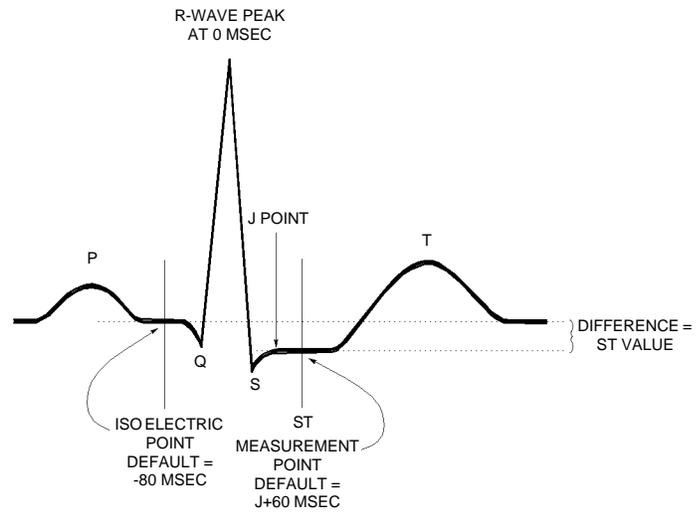
- *ST/AR Algorithm - ST Segment Monitoring* Application Note (4522 981 92851)
- *Information Center Online Instructions for Use and Online Help*

The Measurement

The ST measurement for each beat complex is the vertical *difference* between two measurement points. The **isoelectric point** provides the baseline for the

ST/AR ST Segment Algorithm

measurement and the **ST point** provides the other measurement point. It is positioned with reference to the J-point.



ST/AR ST Segment Algorithm

Algorithm Processing

ST analysis analyzes ECG signals to classify the heart beats. Only beats classified as normal or Supraventricular (atrially paced) are used to calculate ST elevations and depressions.

The ST/AR ST algorithm processing includes special ST filtering, beat selection and statistical analysis, calculation of ST segment elevations and depressions, and lead reconstruction and wave generation.

When ST analysis is being performed on two leads, the averaged derived and reconstructed ST waves and associated ST segment values are given for up to six leads, depending on the type of patient cable:

- 3-wire: one lead
- 5-wire: up to two leads if monitoring a chest and a limb lead
- 5-wire: up to six leads if monitoring two limb leads with the Philips Transmitter (without EASI monitoring)
- 5-wire: up to 12 leads if monitoring using EASI

Note—No ST analysis is done on a patient if an electrode falls off.

Displayed ST Data

ST data displays as values in the Patient Sector and Patient Window. A positive value indicates ST segment elevation; a negative value indicates ST segment depression. You can view ST data in ST Review, Trend Review, and Event Review windows.

EASI ST Analysis

The Information Center generated ST values presented in the patient sector and Patient Window for EASI derived leads is STindx (ST Index). STindx is a summation of three ST segment measurements, using the leads that can indicate ST segment changes in the different locations of the heart:

- anterior lead V2
- lateral lead V5
- inferior lead aVF

Caution

Be sure not to duplicate the lead labels. This can result in incorrect ST values being displayed for those leads.

ST Operation

Turning ST Monitoring On/ Off

The ST Setup Window allows you to turn ST monitoring on or off for all available ECG leads.

To turn ST monitoring on at the Information Center, perform the following steps:

Step	Action
1	From the Patient Window, click the All Controls button.
2	From the All Controls Window, click the ST Setup button.
3	From the ST Setup Window, click ST On .

You would turn ST monitoring off if:

- You are unable to get any lead that is not noisy.
- Arrhythmias such as atrial fib/flutter cause irregular baseline.
- The patient is continuously ventricularly paced.
- The patient has left bundle branch block.

Adjusting ST Measurement Points

The ST Setup Window enables you to adjust the ST measurement points to ensure accurate data.

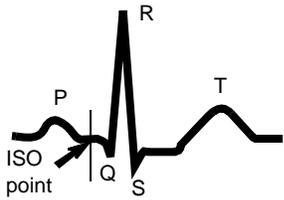
There are three measurement cursors:

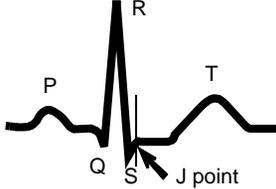
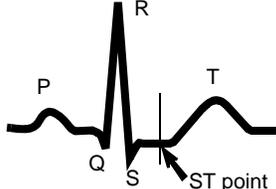
- The ISO measurement cursor positions the isoelectric point in relation to the R-wave peak.
- The J-point cursor positions the J-point in relation to the R-wave peak. The purpose of the J-point is to correctly position the ST measurement point.
- The ST measurement cursor positions the ST point a fixed distance from the J point.

Note—The ST measurement points may need to be re-adjusted if the patient's heart rate or ECG morphology changes significantly.

ST/AR ST Segment Algorithm

Perform the following steps at the Information Center to adjust the ST measurement points:

Step	Action
1	Access the ST Setup window by clicking on the All Controls button in the Patient Window, then clicking on the ST Setup button.
2	If you need to adjust the ISO (isoelectric) point, place the cursor over the ISO button to access the adjustment arrows. Then use the arrows to position the bar in the middle of the flattest part of the baseline (between the P and Q waves or in front of the P wave). 

Step	Action
3	<p>Adjust the J point, if necessary, by placing the cursor over the J-point button to access the adjustment arrows. Then use the arrows to position the bar at the end of the QRS complex and the beginning of the ST segment.</p> 
4	<p>Adjust the ST point, if necessary, by using the J point as an “anchor” and placing the bar at the midpoint of the ST segment. Choices are J+0, J+20, J+40, J+60, or J+80.</p> 

**Establishing
ST Reference
Beats
(Baseline)**

After adjusting the measurement points, you can establish baseline reference beats for all available leads in the ST Review window at the Philips Information Center. Reference beats enable you to compare waveform changes, for example from admission, or prior to or after treatment. The reference continues to be saved beyond the 24 hour review window, but you can update it to any beat within the last 24 hours. Please refer to the Philips Information Center Instructions for Use18

or on-line Help for directions.

**ST Alarm
Settings**

All Philips Information Center alarm settings (limits and on/off status) have unit default settings. The Philips Information Center however, lets you set the high and low ST alarm limits for individual patients based on:

ST/AR ST Segment Algorithm

- Your assessment of the patient's clinical condition.
- Unit protocols.
- Physician orders or medication specified limits.

You can make the following adjustments to ST alarm limits to accommodate the clinical condition of individual patients:

- Turn all alarms off/on.
- Adjust the alarm limits:
 - to specific high and low limits
 - to Smart Limits (see the *Philips IntelliVue Information Center Instructions for Use* for information on Smart Limits)
 - back to unit default settings.

You adjust the ST alarm limits in the ST Alarms Window. Each ST parameter has its own alarm limit. The alarm is triggered when the ST value exceeds its alarm limit for more than 1 minute. The alarm will be a yellow alarm.

When more than one ST parameter is in alarm, only one alarm message displays. For multilead alarms when using an EASI transmitter, an alarm is generated if two or more ST leads exceed the alarm limits. The default setting is +/-1.0. The alarm message indicates the two leads that are in greatest violation of the limits, for example, “**MULTI ST AVR, V6”. If another lead becomes deviant, the message changes but it is considered the same alarm (no new alarm sounds and it is not listed as a new event).

See “Physiologic Alarms” on page 2-9 for a list of all ST alarms.

See *IntelliVue Information Center Instructions for Use* for specifics on alarm management and behavior.

Adjusting ST Alarms

Make adjustments to ST alarms on the ST Alarms window at the Information Center.

Step	Action
1	From the Patient Window, select the All Controls button.

Step	Action
2	From the All Controls window, select the ST Alarms button under Alarm Management and Setup.
3	<p>In the ST Alarms window, adjust alarms as needed. Choices for setting the ST alarm limits are:</p> <p>Unit Settings—Click on this button if want to have the specific limits that are pre-set for your unit.</p> <p>Smart Limits—Click on this button to set high and low limits around your patient's current ST value. The difference above and below the patient's ST value are pre-set for your unit.</p> <p><i>Note</i>—Smart Limits can be configured to automatically be activated when the patient is connected. See the <i>IntelliVue Information Center Instructions for Use</i> for additional information on using smart limits.</p> <p>Specified limits—Use these to set the high and low alarm limits based on your assessment of the patient's clinical condition, unit protocols, or physician orders or medication specified limits. A good guideline is + 1.0 mm or - 1.0 mm from the patient's ST, or follow your unit protocol.</p>

ST/AR ST Segment Algorithm

5

SpO₂ Monitoring

This chapter provides an introduction to the SpO₂ measurement and its application. It includes the following sections:

- SpO₂ Safety Information 5-2
- Pulse Oximetry Measurement. 5-4
- Selecting a SpO₂ Sensor. 5-5
- Applying the Sensor 5-9
- Connecting the SpO₂ Cable 5-14
- Measuring SpO₂ 5-15
- Understanding SpO₂ Alarms 5-20
- Optimizing SpO₂ Measurement Performance 5-21

SpO₂ Safety Information

Warning

Always confirm Information Center observations with clinical observation of the patient before administering interventions.

Prolonged, continuous monitoring can increase the risk of changes in skin characteristics, such as irritation, reddening, blistering or pressure necrosis, particularly on patients with impaired perfusion and varying or immature skin morphology. Specific attention must be given to sensor site inspection for changes in skin quality, proper optical path alignment and attachment. Check the application site at regular intervals and change the site if any compromise in skin quality should occur. More frequent checking can be required due to an individual patient's condition.

Using a sensor during MR imaging can cause severe burns. To minimize this risk, ensure that the cable is positioned so that no inductive loops are formed. If the sensor does not appear to be operating properly, remove it immediately from the patient.

Do not use disposable sensors on patients who exhibit allergic reactions to the adhesive.

Injected dyes such as methylene blue or intravascular dyshemoglobins such as methemoglobin and carboxyhemoglobin can lead to inaccurate (over-estimated) measurements.

Interference leading to inaccurate measurements can be caused by:

- High levels of ambient light (Hint: cover application site with opaque material)**
 - Electromagnetic interference**
 - Excessive patient movement and vibration.**
-
-

Warning

Removal of the SpO₂ sensor during Continuous SpO₂ monitoring results in a NO SENSOR technical alarm. There is no technical alarm for a "No Sensor" condition in Spot Check mode.

**SpO₂
Information
for the User¹**

The pulse oximeter is calibrated to indicate fractional oxyhemoglobin, and displayed results can range from 0 to 100%.

A 10 second averaging filter is used in the calculation of the result. Displayed results are typically updated every second, but the update period can be automatically delayed by up to 30 seconds in the presence of noise.

Physiological SpO₂ alarm signals will be generated at the central station. The SpO₂ low limit can be set between 50 and 99% inclusive, in 1% increments. The SpO₂ high alarm limit can be set between 51 and 100% inclusive, in 1% increments. The maximum delay between the physiological alarm condition and alarm signal generation at the central station is 10 seconds.

Pulse rate is also derived from the pulsatile SpO₂ measurement, and displayed results can range from 30 to 300 bpm. There is no alarm function for pulse rate.

The pleth wave is auto-scaled to maximum display size. It decreases only when the signal quality becomes marginal. Pleth wave size is NOT directly proportional to the pulse volume.

1. A functional tester cannot be used to assess the accuracy of a pulse oximeter sensor or a pulse oximeter monitor. If there is independent demonstration that a particular calibration curve is accurate for the combination of a pulse oximeter monitor and a pulse oximeter sensor, then a functional tester can measure the contribution of a monitor to the total error of a monitor/sensor system. The functional tester can then measure how accurately a particular pulse oximeter monitor is reproducing that calibration curve.

Pulse Oximetry Measurement

The ECG-SpO₂ TRx⁺ Transceiver supports an SpO₂ sensor connection using Fourier Artifact Suppression Technology (FAST). The FAST algorithm overcomes many of the issues associated with traditional pulse oximetry such as sensitivity to patient movement and intense ambient light. The algorithm offers improved motion artifact rejection as well as performance improvements for patients with low perfusion. SpO₂ can be measured continuously, where a value is sent to the Information Center every second, or as a single, individual measurement (Spot Check). The Spot Check measurement will be removed from the Information Center display after 24 hours. If 1-minute or 5-minute sampling rate is selected at TeleMon, the transceiver will provide Continuous SpO₂ measurement after disconnection (see “Transceiver Use with TeleMon A02/A03” on page 1-27).

The SpO₂ parameter measures the arterial oxygen saturation, that is, the percentage of oxygenated hemoglobin in relation to the total hemoglobin.

If, for example, a total of 97% of the hemoglobin molecules in the red blood cells of the arterial blood combine with oxygen, then the blood has an oxygen saturation of 97%. The SpO₂ numeric that appears on the monitor will read 97%. The SpO₂ numeric indicates the percentage of hemoglobin molecules which have combined with oxygen molecules to form oxyhemoglobin.

- The oxygen saturation is measured using the pulse oximetry method. This is a noninvasive method of measuring the arterial hemoglobin oxygen saturation. It measures how much light, sent from light sources on one side of the sensor, travels through patient tissue (such as a finger or an ear), to a receiver on the other side of the sensor.
- The amount of light passing through depends on many factors, most of which are constant, such as tissue or venous blood. However one of the factors, the blood flow in the arterioles, varies with time - because it is pulsatile.

This measurement principle is used to derive the SpO₂ measurement. The numeric that is displayed at the Information Center is the oxygen saturation of the arterial blood - the measurement of light absorption

during a pulsation. Correct placement of the sensor is essential for accurate measurements (see “Applying the Sensor” on page 5-9).

Pulse Indication

During Spot Check measurement, the pulse signal is detected and communicated to you via an auditory signal. The indicator is a single low-pitch tone for each pulse detected. The tone is controlled by the Volume and Mute controls at the Information Center. The pulse indication stops when a measurement is complete. However, since it is possible to have a strong pulse but fail an SpO₂ measurement, you should listen for the successful completion of a measurement (single beep), or a double beep if the measurement fails.

The pulse indicator is for information only, and should not be used as an indication for treatment. The indicator is not functional in Continuous measurement mode.

Clinical Note: If the transceiver is in Spot Check mode and the sensor light is illuminated but you do not hear a low-pitch sound synchronized with the pulse, readjust the sensor, or move the sensor to another site to provide better detection.

Selecting a SpO₂ Sensor

Philips reusable sensors in adult, pediatric and infant models can be used, as well as Philips and Nellcor disposable sensors.

Use only specified sensors (probes) and cables.

The following chart and figure “Selecting an SpO₂ Sensor” on page 5-7 guide you in selecting the correct sensor type. To use the figure, find the patient’s weight on the vertical axes. On the horizontal axis at this weight, the shaded areas indicate that the sensor is a "best choice" for the patient. Unshaded areas indicate a "good choice." For example, the best reusable sensor for a 50 kg patient is the M1191A, applied to the finger or toe. Alternatively, you could use M1194A applied to the ear.

Sensor Type	When to Use
-------------	-------------

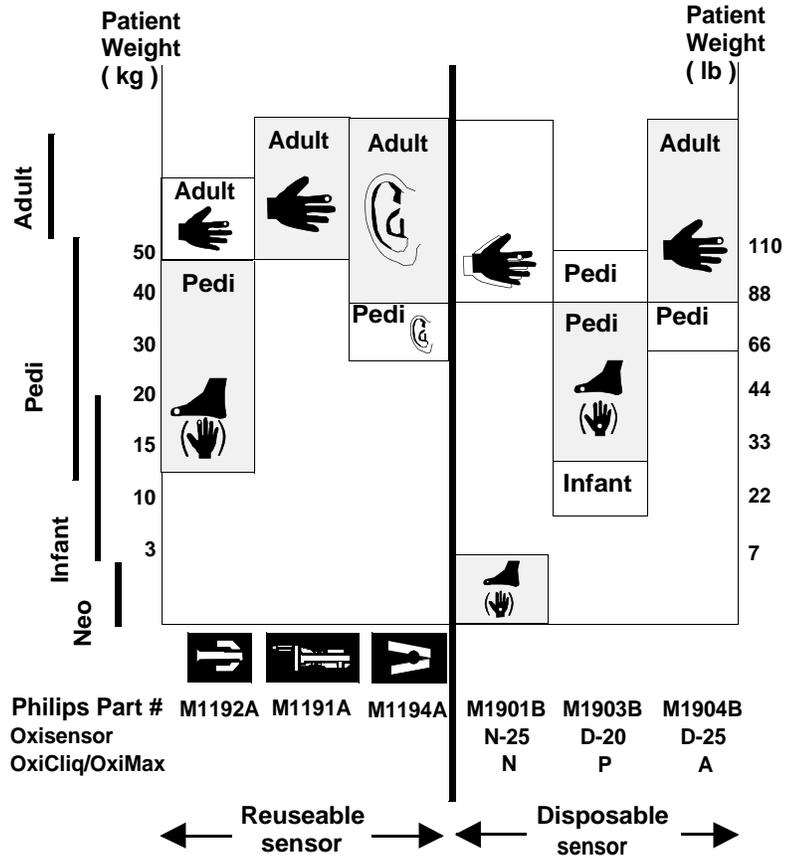
Selecting a SpO2 Sensor

Reusable	<p>You can use reusable sensors on different patients after cleaning and disinfecting them. For care and cleaning instructions, see the instructions accompanying the sensors. Reusable sensors should be changed to another site every 2-3 hours or in accordance with your clinical practice guidelines.</p> <p>See the Directions for Use supplied by Nellcor® Incorporated for instructions on preparation and application of reusable sensors.</p>
Disposable	<p>Use disposable sensors only once and then discard. However, you can relocate them to a different patient-site if the first location does not give the desired results. Do not reuse disposable sensors on different patients.</p> <p>See the Directions for Use supplied by Nellcor® Incorporated for instructions on preparation and application of disposable sensors.</p>

Warning

When the specified Nellcor® sensors are used, the application must be consistent with the sensor manufacturer's own guidelines.

Selecting a SpO₂ Sensor



Preferred sensor types
 Alternative sensor types

Selecting an SpO₂ Sensor

Selecting a SpO2 Sensor

Caution

Do not use OxiCliq disposable sensors in a high humidity environment, or in the presence of fluids. These can contaminate sensor and electrical connections, and thereby cause unreliable or intermittent measurements.

Do not use disposable sensors on patients who have allergic reactions to the adhesive.

If you are using Nellcor® sensors, see the directions for use supplied with these sensors.

Applying the Sensor

Sensor Application Safety Information

Warning

Failure to apply a sensor properly can reduce the accuracy of the SpO₂ measurement.

Loose/Tight sensor: If a sensor is too loose, it can compromise the optical alignment or fall off. If it is too tight, for example because the application site is too large or becomes too large due to edema, excessive pressure can be applied. This can result in venous congestion distal from the application site, leading to interstitial edema, hypoxia and tissue malnutrition. Skin irritations or ulcerations can occur as a result of the sensor being attached to one location for too long.

To avoid skin irritations and ulcerations, inspect the sensor application site every 2-3 hours, and change the application site at least every 4 hours or according to clinical practice guidelines.

Venous Pulsation: Do not apply sensor too tightly as this results in venous pulsation and can severely obstruct circulation and lead to inaccurate measurements.

Ambient Temperature: Never apply an SpO₂ sensor at ambient temperatures from above 37 °C (99 °F) because this can cause severe burns after prolonged application.

Extremities to Avoid: Avoid sites distal to BP cuff or intra-arterial line.

Site Selection

- Avoid sites with impaired perfusion, skin discoloration, excessive motion or nail polish.
- Avoid placing the sensor in an environment with bright lights (if necessary, cover the sensor with opaque material).
- Avoid use of excessive pressure at the application site (e.g., sensor applied too tightly, excessive adhesive tape to secure the sensor, clothing or

Applying the Sensor

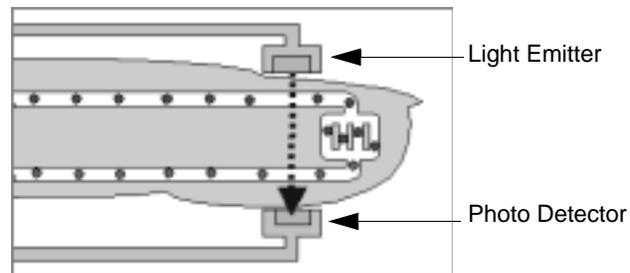
restraints that are too tight). These result in venous pulsations and inaccurate measurement, and may severely obstruct circulation.

Sensor Application

A minimum pulsatile flow must be present at the application site of your patient to obtain measurements.

Select an appropriate sensor and apply the sensor properly to avoid incorrect measurements. Applying a small amount of pressure at the application site can improve the measurement. Use one of the preferred application sites for your sensor. Selecting the most suitable sensor and application site will help you to ensure that:

- The light emitter and the photo detector are directly opposite each other and that all the light from the emitter passes through the patient's tissues,
- The application site is of the correct thickness for light to pass through. If the application site is too thick or too thin, an SpO₂ NON-PULSATILE technical alarm will occur. You should then select another site as appropriate.



Positioning of the Light Emitters and Photo Detector

Inspect the application site every 2 to 3 hours or according to clinical practice guidelines to ensure skin integrity and correct optical alignment. If skin integrity changes, move the sensor to another site.

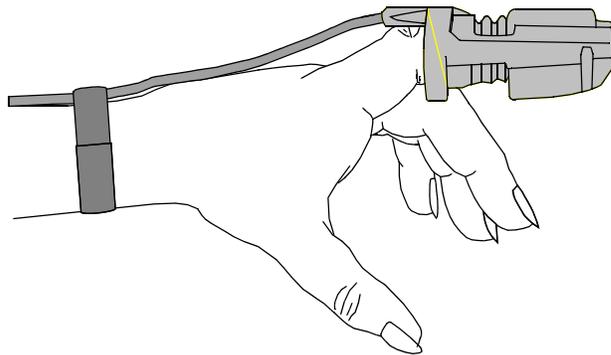
Follow the sensor's instructions for use, adhering to all warnings and cautions.

To apply the sensor, use the following directions.

Step	Action
1	Select the site and appropriate sensor (see “Selecting a SpO2 Sensor” on page 5-5).
2	Apply the sensor to the appropriate part of the patient’s body. <i>Note</i> —The application site should match the sensor size so that the sensor can neither fall off nor apply excessive pressure.
3	Check that the light emitter and the photo detector are directly opposite each other. All light from the emitter must pass through the patient’s tissue.

Adult Finger sensor (M1191A)

Push the sensor over the fingertip in such a way that the fingertip touches but does not protrude from the end of the sensor. The fingertip must be uppermost and the cable must lie on the back of the hand. This ensures that the light sources cover the base of the fingertip giving the best measurement results. The cable can be held in place by the accompanying wristband.



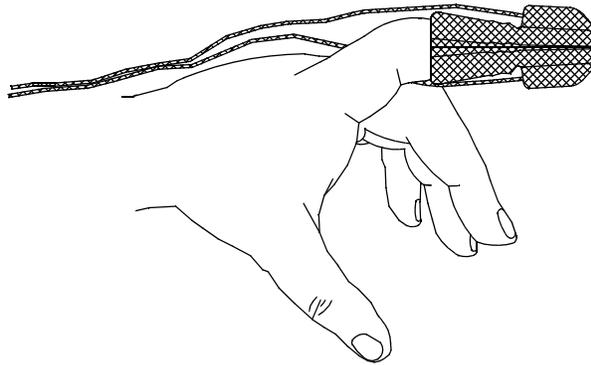
Applying the Sensor

Warning

Failure to apply the sensor properly can cause incorrect measurement of SpO₂. For example, not pushing the sensor far enough over the finger can result in inaccurate SpO₂ readings. Pushing the sensor too far, so that the finger protrudes from the sensor, can pinch the finger, resulting in inaccurately low SpO₂ readings.

**Small Adult/
Pediatric
Finger sensor
(M1192A)**

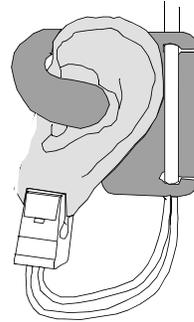
Push the sensor over the fingertip in such a way that the fingertip touches but does not protrude from the end of the sensor.



Note—When using an M1195A Infant Finger/Toe Sensor, select a finger or toe with a diameter of between 7 and 8 mm (0.27 and 0.31 inches).

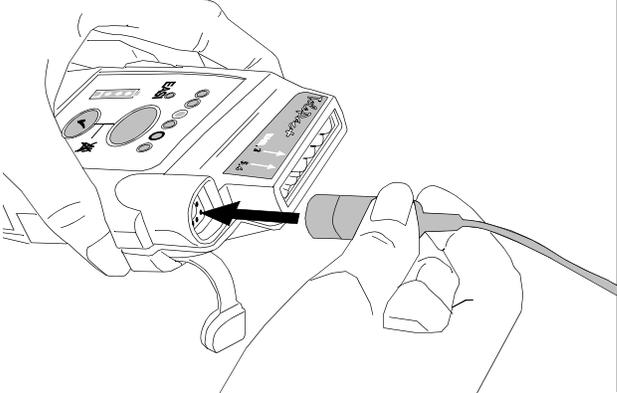
**Ear Clip
sensor
(M1194A)**

Clip the probe onto the fleshy part of the ear lobe as shown in the diagram below. The plastic fixing mechanism helps to minimize artifact generated by patient motion. Do not position the probe on cartilage or where it presses against the head.



The clip sensor can be used as an alternative if the adult finger sensor does not provide satisfactory results. The preferred application site is the ear lobe, although other application sites with higher perfusion (such as the nostril) can be used. Due to the physiologically lower perfusion in the ear lobe, you should be aware of the reduced accuracy of the measurement and more frequent technical alarms.

Connecting the SpO₂ Cable

Step	Action
1	<p>Connect the sensor cable to IntelliVue TRx⁺.</p> <ul style="list-style-type: none">• Connect <i>reusable</i> sensors directly into the transceiver.• Connect <i>disposable</i> sensors into the adapter cable, then connect the adapter cable to the transceiver. Remove the protective backing. 
2	Ensure that the sensor and connector are positioned away from power cables, to avoid electrical interference.
3	Adjust SpO ₂ alarms in the patient Window (see “Telemetry Controls in the Patient Window” on page 6-2).
4	Make other adjustments in the Telemetry Setup Window (see “Patient-Configurable Settings in Telemetry Setup” on page 6-3).

Caution

Extension cables: Do not use extension cables with the IntelliVue TRx⁺.

Electrical Interference: Position the sensor cable and connector away from power cables, to avoid electrical interference.

Measuring SpO₂

SpO₂ measurements can be made continuously in Continuous mode or manually on an as-needed basis in Spot Check mode, depending on the transceiver configuration. While operating in continuous mode, you can also measure pulse, and display the pleth wave at the Information Center. The SpO₂ parameter is turned on by inserting/removing the sensor cable into the transceiver, or by control from the Information Center. SpO₂ monitoring consumes considerable electrical energy. If the battery power is not at least 25% full, no measurements of SpO₂ can be made.

Setting the mode at Continuous or Spot Check is done at TeleMon or is configured using the Service Tool.

Spot Check

When the transceiver is configured for Spot Check measurement, use the following instructions to take an individual, manual SpO₂ reading from the transceiver. You can also initiate a Spot Check measurement in the Patient Window at the Information Center by selecting the **STAT SpO₂** icon.

Note—Spot Check measurements from the transceiver are inactive when the transceiver is connected to TeleMon.

Step	Action
1	Set SpO ₂ mode to Spot Check in the Telemetry Setup window.
2	Attach the sensor to the patient.

Measuring SpO₂

Step	Action
3	<p>Connect the SpO₂ cable to IntelliVue TRx⁺, and check that:</p> <ul style="list-style-type: none"> • The SpO₂ sensor light turns on. • A low-pitch tone detecting each pulse is audible (unless sounds are muted).
4	<p>After approximately 30 seconds, a tone from the transceiver indicates that a measurement has been taken.</p> <p>The value, with the measurement time, is displayed at the Information Center.</p> <p>The sensor light extinguishes.</p> <p>If the measurement was unsuccessful, you'll hear a double beep. Remove the sensor cable and reinsert it to retake the measurement.</p> <p><i>Note</i>—The SpO₂ value and time stamp will remain on the Information Center for 24 hours or until another measurement is taken, with one exception. If the batteries are removed from the transceiver, the Spot Check measurement will be erased from the display, but the SpO₂ measurements will be available in Trend Review.</p>
5	<p>To repeat a Spot Check measurement at the bedside, disconnect then reconnect the SpO₂ cable to the transceiver.</p>

Continuous

When the transceiver is configured for Continuous SpO₂ measurement, use the following directions to initiate Continuous SpO₂ monitoring.

Step	Action
1	Set SpO ₂ mode to Continuous in the Telemetry Setup window.
2	Insert the SpO ₂ cable into the IntelliVue TRx ⁺ , and check that the sensor light turns on.
3	Attach the sensor to the patient.

Step	Action
4	After approximately 15 seconds, the value, with the measurement time, is displayed at the Information Center. <i>Note</i> —There are no sounds associated with continuous SpO ₂ measurement.
5	To discontinue monitoring, set SpO ₂ mode to off at the Information Center.

Note— If the sensor is removed without discontinuing SpO₂ monitoring in the Telemetry Setup Window at the Information Center, an SpO₂ NO SENSOR technical alarm will result.

Displaying Pulse

When operating in Continuous mode, you can view pulse measurements at the Information Center. See “Patient-Configurable Settings in Telemetry Setup” on page 6-3.

Note—If pulse is turned on, the Patient Sector and Patient Window of the Information Center display the label with "T" (for example, Pulse T) to indicate that the measurement was made via telemetry.

Displaying PlethWave

The transceiver can be configured to transmit the pleth wave for display at the Information Center. See “Patient-Configurable Settings in Telemetry Setup” on page 6-3.

SpO₂ Measurement when Connected to TeleMon

When the transceiver is connected to TeleMon:

- The SpO₂ measurement mode is *always* Continuous.

Measuring SpO₂

- You can change the mode. Changes to the mode take effect when the transceiver is disconnected from TeleMon. The following settings will be used:

Mode Set at TeleMon	Mode when Transceiver is Disconnected
Continuous	Continuous
5-minute	Continuous
1-minute	Continuous
Manual	Spot Check

Turning SpO₂ Monitoring Off

To turn SpO₂ monitoring off, disconnect the sensor cable (or adapter cable) from the transceiver. SpO₂ enters a power-down mode after the cable is disconnected from the transceiver, thereby conserving battery life.

SpO₂ should also be turned off at the Information Center. If the transmitter is configured for Continuous SpO₂ measurement and the sensor is removed without turning SpO₂ off, a SpO₂ NO TRANSDUCER technical alarm will result. See

Important—It is important to disconnect the sensor from the transceiver. Unplugging the sensor from an adapter cable that is connected to the transceiver does NOT provide SpO₂ power-down mode.

Turning the SpO₂ Parameter On/Off

You can turn SpO₂ monitoring on/off at the Information Center. See “Patient-Configurable Settings in Telemetry Setup” on page 6-3.

When SpO₂ is turned on, the Patient Sector and Patient Window of the Information Center display a "T" next to the SpO₂ numeric (for example, SpO₂ T 90%) to indicate that the measurement was made via telemetry.

If the transceiver is connected to the TeleMon Companion Monitor, after you turn SpO₂ on, be sure to adjust the sample rate to match your patient's acuity.

When SpO₂ monitoring is turned off, setting the sample rate to Spot Check at TeleMon will help you conserve the transmitter's battery life.

SpO₂ Parameter Auto ON

The SpO₂ parameter is automatically turned on at the IntelliVue Information Center if a manual SpO₂ measurement is initiated at the transceiver while in Spot Check mode or if the SpO₂ sensor is inserted into the transceiver while the transceiver is in Continuous SpO₂ mode.

When a patient is discharged and the transceiver is in Continuous mode, the SpO₂ parameter is turned off. To reactivate the SpO₂ parameter Auto ON feature from the transceiver, remember to do one of the following when a patient is discharged:

- remove the SpO₂ cable from the transceiver, wait 15 seconds, then reinsert the cable

or

- if using TeleMon, reset the transceiver to Manual mode.

Note—The SpO₂ parameter Auto ON feature only needs to be reactivated when the transceiver is in Continuous mode at discharge.

Note—SpO₂ can always be turned on and off at the IntelliVue Information Center.

Understanding SpO₂ Alarms

Warning

If you measure SpO₂ on a limb that has an inflated NBP cuff, a non-pulsatile SpO₂ technical alarm can occur. If the monitor is configured to suppress this alarm, there can be a delay of up to 60 seconds in indicating critical patient status, such as sudden pulse loss or hypoxia.

Physiologic SpO₂ alarms will be generated and displayed at the Information Center. SpO₂ offers high and low limit alarms, and a high priority (red level) oxygen desaturation alarm. The SpO₂ low limit can be set between 50 and 99% inclusive, in 1% increments. The low alarm limit cannot be set below the desat alarm limit. The SpO₂ high alarm limit can be set between 51 and 100% inclusive, in 1% increments.

The maximum delay between the physiologic alarm condition and alarm annunciation at the central station is 10 seconds. This means that the monitor will generate an alarm if the averaged numeric value on the display exists beyond the alarm limit for more than 10 seconds.

Setting the high SpO₂ alarm limit to 100% is equivalent to switching off the high alarm limit. Therefore the upper alarm limit for oxygen saturation must be carefully selected in accordance with accepted clinical practices.

The desaturation limit is set automatically at 10 below the Low Limit.

SpO₂ alarms are non-latching. That is, when an SpO₂ limit is exceeded, if the alarm is not silenced, it will reset automatically if the patient's alarm condition returns within the limits. This reduces the number of times you will need to reset alarms at the Information Center when an alarm condition has been corrected at the patient's side (for example, movement-induced artifact alarms). See Chapter 2, "Alarms" for a list of all SpO₂ alarms.

Optimizing SpO₂ Measurement Performance

Refer to this section on problem situations if you have difficulty getting a signal or obtaining accurate measurements.

Distortion

Ambient light, motion, perfusion or incorrect sensor placement can affect the accuracy of the derived measurements.

Arterial Blood Flow

The measurement depends on the pulsatile nature of blood flow in the arteries and arterioles; with the following conditions arterial blood flow can be reduced to a level at which accurate measurements cannot be made:

- shock
- hypothermia
- use of vasoconstrictive drugs
- anemia

Wavelength Absorption

The measurement also depends on the absorption of particular light wavelengths by the oxyhemoglobin and reduced hemoglobin. If other substances are present which absorb the same wavelengths, they will cause a falsely high, or falsely low SpO₂ value to be measured. For example:

- carboxyhemoglobin
- methemoglobin
- methylene blue
- indocyanine green*
- indiocarmine*

*These chemicals are used in dye dilution cardiac output calculations.

Ambient Light

Very high levels of ambient light can also affect the measurement; an SpO₂ INTERFERENCE message will appear on the display. The measurement quality can be improved by covering the sensor with suitable opaque material.

Care and Cleaning

For care and cleaning instructions, see the instructions accompanying the sensors.

Optimizing Sensor Performance

To get the best results from your SpO₂ reusable sensor:

- Always handle the sensor and cable with care. The soft finger sleeve houses a sensitive electronic device that can be damaged by harsh treatment. Always protect the cable from sharp-edged objects.
- Use the wristband that is supplied with your M1191A sensor. By keeping the cable between the finger sensor and the wristband fairly loose, you will maintain good monitoring conditions.

Normal wear and tear associated with patient movement and regular sensor cleaning naturally mean that your sensor will have a limited lifetime. However, provided you handle the sensor and its cable with care, you can expect useful service from it for up to two years. Harsh treatment will drastically reduce the lifetime of the sensor. Moreover, Philips Medical Systems' warranty agreement shall not apply to defects arising from improper use.

6

Telemetry Functions at the Information Center

This chapter describes the telemetry-specific functions at the Information Center. It includes the following sections. For additional information regarding the operation of the Information Center, consult *IntelliVue Information Center Instructions for Use*.

Note—ST functions performed at the IntelliVue Information Center are described in Chapter 4.

- Telemetry Controls in the Patient Window 6-2
- Telemetry Controls in the Patient Window 6-2
- Patient-Configurable Settings in Telemetry Setup 6-3
- Unit-Configurable Settings 6-7

Telemetry Controls in the Patient Window

The Patient Window at the Information Center (accessed from the Patient Window control in the Patient Sector) includes controls for a number of telemetry operations. For detailed instructions on these operations, see the *IntelliVue Information Center Instructions for Use* or the *Online Help*.

To View ECG, SpO₂ or NBP Alarm Limits

Move the cursor over the HR or SpO₂ label to display the current high and low alarm limits.

To Change ECG, SpO₂ or NBP Alarm Limits

Move the cursor over the High or Low numeric to display up/down arrow controls for adjusting the limit. After adjusting the limit, move the cursor away from the area to dismiss the limit controls.

To Change ECG Waveform Size

Move the cursor over the ECG waveform to display the ECG Waveform Size popup. Select the label from the label list.

To Select Lead Label

Move the cursor over the ECG waveform to display the Lead Selection popup. Select the label from the label list.

Important—Do not set the primary and secondary channels to the same lead.

To Change Va and Vb Lead Default Settings (6-lead only)

Move the cursor over the ECG waveform to display the Lead Selection popup. Select the label from the label list. For Va or Vb, select Va or Vb, then select the lead to be assigned.

Important—Do not set the primary and secondary channels to the same lead.

To Initiate a Spot Check Measurement

Move the cursor over the SpO₂ label. Then click on the Spot Check icon (finger with sensor).

To Initiate Monitor Standby

See instructions under “Standby Mode” on page 2-5.

Locating the Transceiver (Find Device)

The Find Device feature enables you to generate a continuous double tone (two pitches) at the transceiver to assist in locating a missing device. This function is initiated in the Telemetry Setup Window at the Information Center. Find Device requires that the transceiver has good working batteries and is within the coverage area

To locate a transceiver

Step	Action
1	From the Patient Window, select All Controls -> Telemetry Setup .
2	Click the Find Device button to generate a repeated tone at the transceiver.

To silence the sound

Step	Action
1	Press both the Check button to turn off the sound.

Patient-Configurable Settings in Telemetry Setup

The Telemetry Setup window enables you to configure the transceiver for patient-specific settings. To access this window, from the Patient Window click All Controls, then Telemetry Setup.

Patient-Configurable Settings in Telemetry Setup

The following settings can be adjusted in this window.

Patient-Configurable Settings in Telemetry Setup			
Control	Function	Setting Choices	Default
Telemetry Button	Determine the Information Center response when Telemetry Button is pressed.	<i>Nurse Call</i> - generate nurse call alarm <i>Record</i> - generate a recording strip Nurse Call and Record - generate nurse call alarm and recording strip <i>None</i>	Nurse Call
Telemetry Device Volume	Set the volume level for all adjustable sounds on the transceiver. <i>Note—This control is grayed out if configured as such in Unit settings how is this done?.</i>	1 (low), 2, 3, 4, 5 (high)	3
Telemetry Device Volume Mute	Enable/disable all adjustable sounds on the transceiver. <i>This control is grayed out if disabled in Unit Settings.</i>	enable disable (mute)	enable

Patient-Configurable Settings in Telemetry Setup

Patient-Configurable Settings in Telemetry Setup			
Control	Function	Setting Choices	Default
SpO₂ Mode	<p>Determine the transceiver SpO₂ behavior.</p> <p><i>Note—For Off or Spot Check mode, Pulse is automatically set to disable.</i></p>	<p><i>Off</i> - Stops monitoring of the SpO₂ parameter</p> <p><i>Spot Check</i> - Provides manual measurements so the clinician can check as needed. Measurement initiated by plugging the SpO₂ cable into the transceiver or by selecting STAT SpO₂ icon in the Patient Window.</p> <p><i>Continuous</i> - Sends an SpO₂ parameter value to the Information Center every second.</p>	Spot Check

Patient-Configurable Settings in Telemetry Setup

Patient-Configurable Settings in Telemetry Setup			
Control	Function	Setting Choices	Default
Suppress SpO₂ INOPs with NBP	<p>Enable/disable the SpO₂ algorithm to detect NBP running and suppress sending technical alarms from the transceiver for 60 seconds.</p> <hr/> <p>Warning</p> <p>If you measure SpO₂ on a limb that has an inflated NBP cuff, a non-pulsatile SpO₂ technical alarm can occur. If the monitor is configured to suppress this alarm, there can be a delay of up to 60 seconds in indicating critical patient status, such as sudden pulse loss or hypoxia.</p> <hr/>	<p>enable</p> <p>disable</p>	enable
Pleth Wave	<p>Enable/disable the transmission of the Pleth wave (and its subsequent display) to the Information Center. For Continuous SpO₂ mode only.</p> <p><i>Note</i>—When enabled, the Pleth wave will replace the Vb wave in the Patient Window during 6-lead monitoring</p>	<p>enable</p> <p>disable</p>	disable (Pleth is not displayed.)
Pulse	<p>Enable/disable the transmission of the Pulse parameter (and its subsequent display) to the Information Center. For Continuous SpO₂ mode only.</p>	<p>enable</p> <p>disable</p>	disable (Pulse is not displayed.)

Patient-Configurable Settings in Telemetry Setup			
Control	Function	Setting Choices	Default
SpO₂ Alarm	Enable/disable the display of SpO ₂ alarms on the Information Center	enable disable	enable
Unit Settings	Change current settings back to last saved clinical unit settings	(none)	

Unit-Configurable Settings

Unit Settings provide access to clinical configuration items that affect all patients on an Information Center. When unit settings are changed, in general they do not affect current patient settings. A discharge is needed for the settings to take effect, with the following exceptions: standby duration and telemetry frequency. Telemetry specific settings are listed in the following table. They are accessed through All Controls -> Unit Settings -> Telemetry Setup. All other unit settings are described in *IntelliVue Information Center Instructions for Use*.

Unit Settings require a password, and the displays are in English.

Unit-Configurable Settings

Unit Settings - Telemetry Setup			
Control	Function	Settings	Default
Patient Type	Set patient type used for alarm limits	<i>Adult</i> <i>Pediatric</i>	Adult
Telemetry Button	Determine the Information Center response when Telemetry Button is pressed.	<i>Nurse Call</i> - generate nurse call alarm <i>Record</i> - generate a recording strip <i>Both</i> - generate nurse call alarm and recording strip <i>None</i> - ignore button	Nurse Call
Telemetry Device Volume	Set the volume level for all adjustable sounds on the transceiver.	1 (low) to 5 (high)	3
Telemetry Device Volume Mute	Enable/disable all adjustable sounds on the transceiver.	enable (unchecked) = sound disable (checked) = mute	mute
Standby Duration	Sets the standby duration on the device.	Infinite 10 minutes 20 minutes 30 minutes 1 hour 2 hours 3 hours 4 hours	Infinite

Unit Settings - Telemetry Setup			
Control	Function	Settings	Default
Enable Remote Suspend	Enable/disable alarm pause/suspend at the transceiver.	enable disable	disable
Battery Gauge on Information Center	Display/disable a battery gauge for each assigned device on the Information Center. <i>Note</i> —Do not enable if rechargeable batteries are being used.	enable disable	enable (battery gauge is displayed)
SpO₂ Mode	Determine the transceiver SpO ₂ behavior. <i>Note</i> —When the mode is set to <i>Off</i> or <i>Spot Check</i> , Pulse is automatically set to <i>disable</i> .	<i>Off</i> - Stops monitoring of the SpO ₂ parameter <i>Spot Check</i> - Provides manual measurements so the clinician can check as needed. The SpO ₂ measurement is initiated by plugging the SpO ₂ cable into the transceiver or initiated by selecting STAT SpO ₂ icon in the Patient Window. <i>Continuous</i> - Sends an SpO ₂ parameter value to the Information Center every second.	Spot Check

Unit-Configurable Settings

Unit Settings - Telemetry Setup			
Control	Function	Settings	Default
Suppress SpO₂ Inops with NBP	<p>Enable/disable the SpO₂ algorithm to detect NBP running and suppress sending technical alarms from the transceiver for 60 seconds.</p> <hr/> <p>Warning</p> <p>If you measure SpO₂ on a limb that has an inflated NBP cuff, a non-pulsatile SpO₂ technical alarm can occur. If the monitor is configured to suppress this alarm, there can be a delay of up to 60 seconds in indicating critical patient status, such as sudden pulse loss or hypoxia.</p> <hr/>	<p>enable</p> <p>disable</p>	enable
<p>Pleth Wave <i>Note</i>— When Pleth Wave display is enabled, the Pleth wave will replace the Vb wave in the Patient Window during 6-lead monitoring.</p>	<p>Enable/disable the transmission of the Pleth wave (and its subsequent display) to the Information Center. For Continuous Mode only.</p>	<p>enable</p> <p>disable</p>	<p>disable (Pleth is not displayed.)</p>

Unit Settings - Telemetry Setup			
Control	Function	Settings	Default
Pulse	Enable/disable the transmission of the Pulse parameter (and its subsequent display) to the Information Center. For Continuous Mode only.	enable disable	disable (Pulse is not displayed.)
SpO₂ Alarm	Enable/disable the display of SpO ₂ alarms on the Information Center	enable disable	enable
SpO₂ Limits High	Increment/decrement SpO ₂ high alarm limit by 1 (in %).	Limit maximum is 100. Limit minimum is 51 (adult) or 31 (pediatric). High and low limit must be at least 1% apart.	100 (adult, pediatric)
SpO₂ Limits Low	Increment/decrement SpO ₂ low alarm limit by 1 (in %).	Limit maximum is 99. Limit minimum is 50 (adult) or 30 (pediatric). High and low limit must be at least 1% apart.	90 (adult, pediatric)
3-wire	Set the unit default lead label.	I, II, III	II
5-wire, ECG1	Set the unit default lead label.	I, II, III, MCL, AVR, AVL, AVF, V	II
5-wire, ECG2	Set the unit default lead label.	I, II, III, MCL, AVR, AVL, AVF, V	V
5-wire, ECG3	Set the unit default lead label.	I, II, III, V	III

Unit-Configurable Settings

Unit Settings - Telemetry Setup			
Control	Function	Settings	Default
6-wire, Va	Set the unit default lead label.	V ₁ , V ₂ , V ₃ , V ₄ , V ₅ , V ₆ , V ₇ , V ₈ , V ₉ , V _{3R} , V _{4R} , V _{5R} <i>Note</i> —If ECGx matches Va, then as Va is changed, ECGx changes also.	V ₂
6-wire, Vb	Set the unit default lead label.	V ₁ , V ₂ , V ₃ , V ₄ , V ₅ , V ₆ , V ₇ , V ₈ , V ₉ , V _{3R} , V _{4R} , V _{5R} <i>Note</i> —If ECGx matches Vb, then as Vb is changed, ECGx changes also.	V ₅
6-wire, ECG1	Set the unit default lead label.	I, II, III, MCL, AVR, AVL, AVF, V ₁ , V ₂ , V ₃ , V ₄ , V ₅ , V ₆ , V ₇ , V ₈ , V ₉ , V _{3R} , V _{4R} , V _{5R}	II; V lead choice is determined by Va and Vb settings.
6-wire, ECG2	Set the unit default lead label.	I, II, III, MCL, AVR, AVL, AVF, V ₁ , V ₂ , V ₃ , V ₄ , V ₅ , V ₆ , V ₇ , V ₈ , V ₉ , V _{3R} , V _{4R} , V _{5R}	V ₂ ; V lead choice is determined by Va and Vb settings.
6-wire, ECG3	Set the unit default lead label.	I, II, III, MCL, AVR, AVL, AVF, V ₁ , V ₂ , V ₃ , V ₄ , V ₅ , V ₆ , V ₇ , V ₈ , V ₉ , V _{3R} , V _{4R} , V _{5R}	III; V lead choice is determined by Va and Vb settings.

Unit Settings - Telemetry Setup			
Control	Function	Settings	Default
6-wire, ECG4	Set the unit default lead label.	I, II, III, MCL, AVR, AVL, AVF, V ₁ , V ₂ , V ₃ , V ₄ , V ₅ , V ₆ , V ₇ , V ₈ , V ₉ , V _{3R} , V _{4R} , V _{5R}	V ₅ ; V lead choice is determined by Va and Vb settings.
5-wire EASI, ECG1	Set the unit default lead label.	I, II, III, AVR, AVL, AVF, V ₁ , V ₂ , V ₃ , V ₄ , V ₅ , V ₆	II
5-wire EASI, ECG2	Set the unit default lead label.	I, II, III, AVR, AVL, AVF, V ₁ , V ₂ , V ₃ , V ₄ , V ₅ , V ₆	V ₂

Unit-Configurable Settings

6-14 Telemetry Functions at the Information Center

Maintenance & Troubleshooting

All installation tasks are performed by Service personnel and are described in detail in the service documentation accompanying the system. This chapter provides procedures for maintaining the equipment, assigning labels for replacement transceivers, keeping the transceiver clean, and troubleshooting common problems. It includes the following sections:

- Maintenance 7-2
- Transceiver Cleaning, Disinfection, & Cross-Infection Prevention . . . 7-4
- Troubleshooting 7-15

Maintenance

Basic Monitoring

Before beginning monitoring on a patient:

- Check for any mechanical damage.
- Check all the external leads, plug-ins and accessories.
- Check all the functions of the instrument which are needed to monitor the patient.
- Ensure that the instrument is in good, working order.

Do not use the Philips IntelliVue Telemetry Monitoring System for any monitoring procedure on a patient if you identify features which demonstrate impaired functioning of the instrument. Contact the Service Provider.

Warning

Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.

Label Assignment for Replacement Transceiver

In order to operate within the wireless system, each telemetry device must have an equipment label assigned at the Information Center. The Assign Label function enables you to unassign a label from a lost transmitter, and re-assign that label to a replacement transmitter. Labels are limited to those available in an individual clinical unit. The Label Assignment function requires a password for access, and its controls are available in English only.

To Re-assign a Label from a (Lost) Device to a Replacement Transceiver

Step	Action
1	<p>Clear the sector that the original Equipment Label was assigned to. (Patient Window -> Sector Setup -> Clear the Sector).</p> <p><i>Note</i>—This step ensures that no patient is being monitored by the original (lost) device.</p>
2	Select All Controls, then Label Assignment.
3	<p>Enter password.</p> <p><i>Note</i>—The remaining screens will be in English only.</p>
4	<p>Insert batteries into the replacement device.</p> <p>You should hear a double beep, indicating that the transceiver has no Equipment Label assigned.</p>
5	<p>Select the MAC address of the replacement device from the “New Devices” list.</p> <p><i>Note</i>—The transceiver MAC address is located inside the battery compartment.</p>
6	Select the Equipment Label that was assigned to the unit’s former device from “Devices Labels” list.

Transceiver Cleaning, Disinfection, & Cross-Infection Prevention

Step	Action
7	<p>Select Assign Label to initiate programming of the Equipment Label into the replacement telemetry device</p> <p>- AND -</p> <p>within 10 seconds, press the Check button on the telemetry device.</p> <p><i>Note</i>—If 10 seconds pass without a button push, then repeat this step.</p> <p>What about clicking OK at the prompt? THIS LABEL HAS ALREADY BEEN ASSIGNED TO A PWD WITH A DIFFERENT MAC ADDRESS.</p> <p>When the telemetry device has completed the normal power-up sequence, an “Assignment Complete” message is displayed and the the label is marked as being assigned.</p> <p>The device is now ready to connect to the wireless network.</p>
8	<p>Go back into Sector Setup, and select the Bed Label and Equipment Label, followed by OK. The transceiver is now ready for patient monitoring.</p>

Transceiver Cleaning, Disinfection, & Cross-Infection Prevention

The procedures in this section keep the transceiver clean and provide protection against infectious agents and bloodborne pathogens. Both the outside of the transceiver and the inside of the battery compartment must be kept free of dirt, dust, and debris. The procedures in this section cover the following activities:

- **Cleaning:** removing visible surface decontamination from the device

Transceiver Cleaning, Disinfection, & Cross-Infection Prevention

- **Disinfection:** protecting cleaned devices against infectious agents and bloodborne pathogens by a chemical agent.
- **Cross-Infection Prevention:** using ETO gas treatment to decontaminate cleaned equipment.

Important—After exposure, the transceiver must be cleaned, followed by either Disinfection or Cross-Infection Prevention procedures according to hospital protocols, before continued use in monitoring.

Cleaning the Transceiver

Caution

Do not use any abrasive cleaning materials or overly vigorous cleaning actions on any part or component of the IntelliVue TRx or TRx⁺ transceiver. Use of abrasive cleansers and abrasive cleaning actions will damage the components.

Perform the following steps to clean the transceiver of visible surface contamination.

Step	Action
1	Remove the batteries and any cables or accessories.
2	Soak the transceiver in water for up to 5 minutes to soften any dried debris, if necessary.
3	Rinse the transceiver in water.
4	Flush device orifices with a forceful water stream to remove any residue in the openings.
5	Allow to air-dry, or dry with a non-lint producing cloth.
6	Continue with either Disinfection or Cross-Infection Prevention procedure, according to your hospital's protocol.

Disinfecting the Transceiver

Warning

To prevent fire, provide adequate ventilation and do not permit smoking when disinfecting the device with a flammable liquid, such as alcohol.

Caution

Remove the batteries and any cables or accessories before you disinfect the transceiver.

The transceiver can be disinfected by two methods: wiping or soaking. If the device has areas that are difficult to disinfect, soaking for up to five minutes is recommended. The approved disinfection agents are:

- Isopropyl Alcohol, $\geq 70\%$
- Sodium Hypochlorite, 10% solution prepared within 24 hours (for wiping only)

Equipment must be cleaned (see “Cleaning the Transceiver” on page 7-5) before this disinfection by wiping or soaking is performed.

Wiping the Transceiver

Step	Action
1	Remove the batteries and any cables or accessories.
2	Wipe the transceiver clean by using a cloth dampened modestly with one of the following approved cleaning agents: <ul style="list-style-type: none">• Isopropyl Alcohol ($\geq 70\%$)• Sodium Hypochlorite (chlorine bleach), 10% solution prepared within 24 hours.

Transceiver Cleaning, Disinfection, & Cross-Infection Prevention

Step	Action
3	Wipe all disinfected surfaces with distilled water to remove any residue.
4	Allow to air-dry, or dry with a non-lint producing cloth.

Soaking the Transceiver

Caution

Do not soak the equipment in cleansers other than Isopropyl Alcohol, or soak longer than five minutes. Soaking the transceiver for longer than five minutes or in cleansers other than Isopropyl Alcohol can severely damage the device.

Step	Action
1	Remove the batteries and any cables or accessories.
2	Soak the device in Isopropyl Alcohol ($\geq 70\%$) for up to five minutes. <i>Note</i> —The battery compartment can be closed or open during soaking.
3	Dip all cleaned surfaces in bowl of distilled water to remove any residue.
4	Dry the equipment with a non-lint producing cloth.

Cross-Infection Prevention for the Transceiver

The transceiver can be subjected to one ETOH cross-infection prevention process four times per year for 2 years. Completion of this procedure achieves a cross-infection prevention assurance level of $10E-6$.

Equipment must be cleaned (see “Cleaning the Transceiver” on page 7-5) before this procedure is performed.

Transceiver Cleaning, Disinfection, & Cross-Infection Prevention

Note—If there is concern over cross-contamination due to leadsets or sensors, new leadsets or sensors should be used.

Equipment and Materials

Warning

EO is highly explosive, toxic, and a potential occupational carcinogenic and reproductive hazard. Handle it with extreme care, following U.S. Occupational Safety and Health Administration (OSHA) standards for EO (29 CFR 1910.1047)*. Personnel exposure and/or room air must be monitored per OSHA standards.

Vent sterilizer gas outdoors or to a suitable, evacuated container for reprocessing, depending upon state, provincial, or country environmental regulations. Do not vent sterilant indoors.

Vent aerator exhaust only to the outdoors.

* See “References” on page 7-12.

Transceiver Cleaning, Disinfection, & Cross-Infection Prevention

Use the following equipment and material to process the transceiver:

1. Ethylene Oxide (Allied Signal Oxyfume-2002™), heretofore referred to as EO.
2. Gas sterilizer, made by American Sterilizer Company or other manufacturers.
3. Mechanical aerator. The intake air for the aeration chamber must be routed through bacterial filters, and the exhaust air must be vented outside the building.

Note—Available combination sterilizer/aerators bypass the problem of personnel exposure to EO during transfer of treated material to a separate aeration cabinet.

Cross- Infection Process

The following generic procedure can be used to supplement the sterilizer and aerator manufacturers' instructions, although the processing times, temperatures, and pressure must be the same as those given in this procedure.

Important—In order to complete this stage of the process safely, harmful residue gas must be dissipated through aeration.

Step	Action
1	Remove any obvious contamination from the equipment to be processed using approved cleaners.
2	Individually package each transceiver in standard central supply room (CSR) wrapping material secured with EO color-change indicator tape.
3	Apply -26 inHg +/- 1 (-12.77 psig +/- .49) vacuum to the empty sterilizer chamber two times, to remove any residual EO or moisture. Vent the vacuum pump to the outdoors to avoid toxic hazards to personnel.
4	Insert the equipment to be processed into the gas sterilizer.
5	Heat the chamber and its contents to 54.4 +/- 2.8°C (130 +/- 5°F).
6	Apply -26 inHg +/- 1 (-12.77 psig +/- .49) vacuum to the sterilizer chamber.

Transceiver Cleaning, Disinfection, & Cross-Infection Prevention

Step	Action
7	Humidify the chamber at 50% +/- 10% relative humidity for 20 to 30 minutes.
8	<p>Taking a minimum of five minutes, slowly introduce EO sterilant until the sterilizer unit pressure gauge reaches 11 +/- 1 psig.</p> <p><i>Note</i>—At this pressure, the concentration of sterilant in the chamber will be 600 +/- 50 mg/liter, regardless of the chamber size.</p>
9	<p>Process the equipment to be processed as follows:</p> <p style="padding-left: 40px;">Pressure: 11 +/- 1 psig (established in the preceding step).</p> <p style="padding-left: 40px;">Time: 2-3 hours</p> <p style="padding-left: 40px;">Temperature: 54.4 +/- 2.8°C (130 +/- 5°F)</p>
10	<p>Extract the gas mixture from the sterilizer as follows:</p> <hr/> <p>Warning</p> <p>Comply with OSHA standards*. Do not vent sterilizer gas to the room, but vent only outdoors or to a suitable, evacuated container, depending upon state, provincial, or country environmental regulations. (If the mixture is captured, it can be separated commercially and the component gases re-used.)</p> <p>* See “References” on page 7-12.</p> <hr/> <p>a. Pump the gas mixture out of the chamber until you obtain a vacuum of -26 inHg +/- 1 (-12.77 psig +/- .49), returning the mixture to a suitable evacuated container.</p> <p>b. Return the sterilizer chamber to ambient pressure by introducing air that has been bacterially filtered.</p>

Transceiver Cleaning, Disinfection, & Cross-Infection Prevention

Step	Action
11	Air-wash the chamber and material as follows: <ul style="list-style-type: none">a. Apply -26 inHg +/- 1 (-12.77 psig +/- .49) vacuum to the chamber and processed material again, to remove residual EO. The vacuum pump must be vented to the outdoors.b. Return the sterilized chamber to ambient pressure by introducing air that has been bacterially filtered.
12	Continue with the "Aeration Procedure" (following).

**Aeration
Procedure**

Warning

To avoid chemical burns and toxic effects, the equipment must be aerated after sterilization, as described. The aerator must have bacterial filters and outdoor venting.*

See "References" on page 7-12.

Transceiver Cleaning, Disinfection, & Cross-Infection Prevention

Aerate the processed equipment by performing the following steps:

Step	Action
1	To dissipate residual EO, aerate the processed equipment with air that has been bacterially filtered, using a mechanical aerator or combination sterilizer/aerator as follows: ¹ Time: 8-9 hours Temperature: 54.4 +/- 2.8°C (130 +/- 5°F) Ventilation Frequency: At least 30 air exchanges per hour.
2	Continue with the “Test Procedure” (following).

¹ These values will produce EO and Ethylene Chlorohydrin residual levels in the transceiver and patient cable plastic that meet ISO 10993-7 in conjunction with AAMI Technical Information Report 19, that the FDA currently endorses.

References

OSHA: Standard for acceptable levels of personnel exposure to Ethylene Oxide Gas: 1 ppm on an eight-hour time-weighted average basis.

Reference: U.S.A. Federal Regulations 49 FR 25734/29 CFR Part 1910.1047, June 22, 1984; final approval 50 FR 9800/2- CFR Part 1910.1047, March 12, 1985.

Test Procedure

Caution

You must perform this test each time you put a transceiver through the cross-infection prevention procedure.

This test allows you to verify that patient information for both ECG and SpO₂ (if you are monitoring pulse oximetry) appear at the information center and at the bedside. You can use this procedure with a patient simulator.

Transceiver Cleaning, Disinfection, & Cross-Infection Prevention

Note—This test assumes that the telemetry system and Information Center are fully installed, and that you have performed the procedure to learn the transceiver identity code.

Test the transceiver by performing the following steps. If the test indications do not appear, refer to your Service Provider.

Step	Action
1	Perform a mechanical inspection of the transceiver (connectors, battery door opening and closing, Telemetry and Check buttons).
2	At the Information Center, select the telemetry bedside you are testing.

Transceiver Cleaning, Disinfection, & Cross-Infection Prevention

Step	Action
3	<p>Test the transceiver:</p> <ul style="list-style-type: none"> a. Put fresh batteries in the transceiver and close the battery door Result: All six lead lights should flash, and one light should remain on. b. Attach a leadset to the ECG port, and attach an SpO₂ sensor to the SpO₂ port. If an ECG simulator is available, attach the ECG leads to the simulator and the SpO₂ sensor to yourself. At TeleMon, set the SpO₂ sample rate to Continuous. Result: An ECG trace and SpO₂ information should be visible on the Information Center display. All transceiver lights should be off. c. Disconnect the Right Arm lead for standard ECG or the “I” electrode for EASI. Result: The RA LED or the “I” lead LED should turn on, and a Leads Off INOP should appear on the display at the Information Center. d. Reconnect the electrode.
4	<ul style="list-style-type: none"> a. Connect the transceiver to TeleMon and observe the ECG waveform and SpO₂ numerics on the TeleMon display. Result: The ECG waveform and SpO₂ numerics should be displayed on the TeleMon screen.

Troubleshooting

Basic Troubleshooting

For problems with...	see...
<ul style="list-style-type: none"> • ECG measurement 	<p>“Optimizing ECG Measurement Performance” on page 3-25</p> <p>“Technical Alarms (INOPs)” on page 2-14</p>
<ul style="list-style-type: none"> • SpO₂ measurement 	<p>“Optimizing SpO₂ Measurement Performance” on page 5-21</p> <p>“Optimizing Sensor Performance” on page 5-22</p> <p>“Technical Alarms (INOPs)” on page 2-14</p>
<ul style="list-style-type: none"> • Batteries 	<p>“Battery Information” on page 1-19</p> <p>“Self Test” on page 1-17</p>
<ul style="list-style-type: none"> • Nurse call 	<p>Nurse Call may have been turned off for the patient. See “Patient-Configurable Settings in Telemetry Setup” on page 6-3 for directions on how to turn it on.</p>

Testing Alarms

Visual and auditory alarms appear at the Information Center. One method of verifying visual and auditory alarms at the Information Center is to connect the transceiver to an ECG or ECG/SpO₂ simulator. By varying the ECG rate and SpO₂ value, alarms can be generated and confirmed for proper operation.

Information Signals

If there is a connection failure within the IWN/Philips IntelliVue Telemetry System, an information signal will be generated. This information signal will be displayed on the Information Center where the affected wireless patient

Troubleshooting

monitoring device(s) (transceiver, access point, access point controller, portable bedside monitor) is assigned, as well as on all other Information Centers connected to a common Database Server.

The condition causing the failure will be described in the Wireless Status Log, which is available in Service Mode. See the tables below.

Information Signal

Information Signal	Description	What to Do
<p>Wireless monitoring loss - Contact Service</p> <p><i>Note</i>—This information signal appears on ALL Information Centers connected to a common Database Server.</p>	<p>Intermittent disruption or failure in communications between one or more patient monitoring wireless devices and the Information Center.</p>	<p>Contact Service.</p> <p><i>Note</i>—Details about the communication disruption are available in the Wireless Status Log (see following table).</p>

Wireless Status Log Messages

Note: CTS refers to Philips IntelliVue Telemetry System.

Wireless Status Log Text	Cause	Notes
CTS Near Area Capacity <ap name>	AP is near usable capacity.	Alert cleared when number of connects is below configured threshold.
CTS Tele AP Malfunction <ap name>	Alert sent when AP DECT processor fails or when a software fault is detected.	No alert is sent when AP ethernet fails.

Wireless Status Log Messages

Note: CTS refers to Philips IntelliVue Telemetry System.

Wireless Status Log Text	Cause	Notes
CTS TELE APC Malfunction <apc name>	Alert sent when this AP detects that its partnered APC has failed.	Alert cleared when master APC sees the keep-alive or registration message from that APC again.
CTS Tele Duplicate IP Address <device name>	Duplicate IP address has been detected on the CTS network.	Alert cleared when all AP have unique IP address
CTS Excessive ARQ retries <device name>	Sent when the number of retries at ARQ level exceeds the specified threshold.	
CTS Tele Excessive Handover <ap name>	Excessive handover of the transceiver.	Alert cleared when handovers per minute is below configured threshold.
CTS Tele Master APC Malfunction	Alert sent when the AP cannot find a master APC.	Alert cleared when AP receives an announcement packet again.
CTS Tele Max Area Capacity <ap name>	Alert sent when the AP reaches maximum capacity.	Alert cleared when number of connects is reduced below maximum limit.
CTS Tele NO SYNC <ap name>	Loss of local or remote sync to Access Points	
Excessive Data Loss <ap name>	Excessive data loss on link.	Alert cleared when data loss is below configured threshold.

Troubleshooting

Safety Standards & Specifications

This chapter describes the regulatory standards that the product complies with, along with product and measurement specifications. It includes the following sections:

- Regulatory Information 8-2
- Battery Life Specifications 8-5
- Electromagnetic Compatibility 8-6
- Radio Specifications 8-8
- Physical Specifications 8-11
- Measurement Specifications 8-13

Regulatory Information

Intended Use The device is intended to provide ambulatory and bedside monitoring of ECG and SpO₂ parameters of adult and pediatric patients in professional healthcare facilities. It is intended to be used by trained healthcare personnel. It is not intended for home use.

This device is a US-only device and is not for use in Canada or the European Union.

Indications for Use Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. Intended for monitoring, recording and alarming of multiple physiological parameters of adult and pediatric patients in transport and hospital environments.

Rx Federal Law restricts this device to sale by or on the order of a physician.

Patient Population This device is not for use with infant or neonatal patients.

Use of the transceiver is restricted to one patient at a time.

The transceiver and related accessories are in compliance with the relevant requirements of EN ISO 10993-1 for Biocompatibility. The transmitter is not designed for direct contact with the patient's skin. The accompanying pouch is the appropriate means for holding the transmitter.

Safety Standards The device complies with the following safety requirements for medical electrical equipment:

- IEC 601-1:1988 + A1:1991 + A2:1995 General Requirements for Safety (with worldwide deviations, including U.S. deviations)
- IEC 60601-1-1:2000 System Safety
- IEC 60601-1-2:2001 Electromagnetic Compliance
- IEC 60601-1-4:1996 Safety for Programmable Electrical Medical Systems
- IEC 60601-2-49:2001 Multi-parameter Monitor Safety

- ISO 10993-1:2003 Biocompatibility (for lead wires and pouch)
- ISO 9919:1992 Pulse Oximeters
- EN 865:1997 Particular Requirements for Pulse Oximeters
- AAMI EC 13:2002 Performance Standard, Cardiac Monitors

Essential Performance

The IntelliVue Telemetry System provides Essential Performance (EP) under normal operating conditions (includes EMC exposure) only as a complete Medical Electrical System, consisting of the M4841A Transceiver, the M2636 TeleMon with Option A02/A03 Companion Monitor (optional), the IntelliVue Telemetry Network Infrastructure, and the M3150A Information Center.

The Philips IntelliVue Telemetry System achieves its Essential Performance exclusively through alarm generation at the M3150 Information Center.

The Philips IntelliVue Telemetry System protects the patient from unacceptable immediate clinical risk by generating specific Physiological Alarms when appropriate. If the System cannot generate Physiological Alarms, then relevant Severe or Hard Technical Alarms (Inoperative Conditions) will be created.

System Classification

The M4841A Transceiver is an FDA Class II device. It has the following characteristics.

Characteristic	Definition
Internally Powered Equipment	The M4841A transceiver is an internally powered device.
Continuous Operation	All equipment is Ordinary Equipment, IPX0, and provides continuous operation
Type CF Defibrillation Proof	The M4841A transceiver is Type CF Defibrillation Proof relative to ECG and SpO ₂ patient applied parts.

Regulatory Information

Characteristic	Definition
Water Resistance	<p>When placed inside a Philips carrying pouch with the flap closed and snaps secured, the M4841A transceiver is rated IPX3 as per IEC 60529:1989 (+A1:1999): Protected against spraying water.</p> <p>The combination of the transceiver and pouch will withstand showering for up to 10 minutes.</p> <p>The transceiver will not be damaged if it is accidentally immersed in liquid for up to 5 minutes.</p> <hr/> <p>Warning</p> <hr/> <p>If the transceiver is used while showering a patient or is accidentally submerged in liquid, detection of leads off conditions may be compromised. Appropriate clinical precautions must be taken.</p> <hr/>

FCC Compliance (USA only)

Operation of this equipment requires the prior coordination with a frequency coordinator designated by the FCC for the Wireless Medical Telemetry Service.

The transceiver and the Philips IntelliVue Telemetry System are subject to radio frequency interference. In the event of suspected radio frequency interference with your device, contact your Service Provider. The FCC requires the following statement for this device:

The Philips IntelliVue Telemetry System complies with Part 15 of the Federal Communications Commission (FCC) Rules. Operation is subject to the following two conditions:

- 1. This device may not cause harmful radio frequency interference to a primary licensed user (radio and television stations), and*
- 2. This device must accept any interference received from a primary licensed user, including interference that may cause undesired operation.*

Pursuant to Part 15.21 of the FCC Rules, any changes or modifications to this equipment not expressly approved by Philips Medical Systems may cause harmful radio frequency interference, and void your authority to operate this equipment.

AC Power Source

The system is not intended for connection to the public mains as defined in CISPR11.

Battery Life Specifications

Battery Type

Equipment	Specification
Battery Type	2 fresh AA disposable alkaline batteries

Battery Life

Note—The battery life specifications listed below are based on Duracell MN 1500 batteries. Battery life for other brands may differ.

Operating Mode	Battery Life
ECG Only	48.7 hours
ECG/SpO ₂ Continuous	16.8 hours
ECG/SpO ₂ Spot Check	between 16.8 hours and 48.7 hours, depending on usage rate

Battery Gauge

Battery Gauge	Approximate Battery Life Remaining	Approximate Operating Time Remaining	Disabled Functions
4 green indicators	> 75%	> 34.7 hours	—
3 green indicators	> 50%	> 23.1 hours	—
2 green indicators	> 25%	> 11.6 hours	—
1 green indicator	25% to Low Battery level	> 15 minutes	—
1 red indicator	Low Battery level to Replace Battery level	< 15 minutes	SpO ₂
no indicator	Replace Battery level (Check batteries for correct polarity)	none	Transceiver shutdown/ RF shutdown

Electromagnetic Compatibility

Medical electrical equipment can either generate or receive electromagnetic interference. This product has been evaluated for electromagnetic compatibility (EMC) with the appropriate accessories according to IEC 60601-1-2:2001, the international standard for EMC for medical electrical equipment. This IEC standard has been adopted in the European Union as the European Norm, EN 60601-1-2:2001.

Radio frequency (RF) interference from nearby transmitting devices can degrade performance of the product. Electromagnetic compatibility with surrounding devices should be assessed prior to using the product.

Fixed, portable, and mobile radio frequency communications equipment can also affect the performance of medical equipment. See your Service Provider for assistance with the minimum recommended separation distance between RF communications equipment and the product.

The cables, sensors/transducers, and other accessories for which compliance is claimed are listed in the Service and User documentation accompanying the product.

Warning

The use of accessories, transducers and cables other than those specified in the product service and user documentation can result in increased emissions or decreased immunity of the product.

Warning

The product should not be used next to or stacked with other equipment. If you must stack the product or , you must check that normal operation is possible in the necessary configuration before the product is used.

Reducing Electromagnetic Interference

The transceiver and associated accessories can be susceptible to interference from other RF energy sources and continuous, repetitive, power line bursts. Examples of other sources of RF interference are other medical electrical devices, cellular products, information technology equipment, and radio/television transmission. If interference is encountered, as demonstrated by artifact on the ECG or dramatic variations in physiological parameter measurement values, attempt to locate the source. Assess the following:

- Is the interference due to misplaced or poorly applied electrodes or sensors? If so, re-apply electrodes and sensors correctly according to directions in *Chapter 3. ECG Monitoring*.

Radio Specifications

- Is the interference intermittent or constant?
- Does the interference occur only in certain locations?
- Does the interference occur only when in close proximity to certain medical electrical equipment?
- Do parameter measurement values change dramatically when the AC line cord is unplugged?

Once the source is located, attempt to attenuate the interference by distancing the transceiver from the source as much as possible. If assistance is needed, contact your local service representative.

Restrictions for Use

Artifact on ECG and other physiological waveforms caused by electromagnetic interference should be evaluated by a physician or physician authorized personnel to determine if it will negatively impact patient diagnosis or treatment.

Radio Specifications

M4841A Transceiver

Parameter	Specification
Frequency Ranges	Bands 1395-1400 MHz and 1427-1432 MHz Channel Spacing: 1.6 MHz
RF Output Power	8 dBm +2/-3 dB (3.2 mW to 10 mW), into Antenna load @ nominal battery voltage
RF Output Power control	<ul style="list-style-type: none">• Transceiver chain gain shall be calibrated at time of manufacture (env temp 25+/- 5 °C)• Over power algorithm deployed to prevent excess power and also includes temperature compensation.

Parameter	Specification
RF Overpower trip point	> 10 dBm
Transceiver Frequency Accuracy during normal operation	+/- 15 kHz relative to channel frequency, includes temperature compensation and aging effects
Reference Frequency Calibration	< 4 ppm set a time of manufacture (env temp 25 +/- 5 °C)
Modulation Type	FSK with Root Raised Cosine filtering
Modulation Deviation	Bit 1: +288 kHz +/- 25 kHz relative to channel frequency Bit 0: -288 kHz +/- 25 kHz relative to channel frequency
Transmitter Output Broadband Noise	<-58.9 dBm in 1 MHz band, outside channel in use
Out of Band Spurious Emission Levels <= 1394 MHz, >= 1401 MHz <= 1428 MHz, >= 1433 MHz	<-41 dBm in 1 MHz bandwidth for FCC limit Limits measured into 50 Ohms load: (< -43 dBc referred to transceiver power of +8 dBm over 25 °C to 55 °C, excluding duty cycle effects defined below) (< -40 dBc over 0 °C to <25 °C, excluding duty cycle effects defined below) Transceiver duty cycle reduces effective spurious emissions: Transceiver RM at 1/64 duty cycle = 18 dB reduction Access Point RM at 16 connections, 50% duty cycle = 6 dB reduction

Radio Specifications

**WMTS
Channel
Frequencies**

**1395 to 1400
MHz**

Parameter	Specification
Lower band edge	1395 MHz
Channel 1	1395.8977 MHz
Channel 2	1397.4970 MHz
Channel 3	1399.0963 MHz
Upper band edge	1400 MHz
Channel spacing	1.6 MHz

**1427 to 1432
MHz**

Parameter	Specification
Lower band edge	1427 MHz
Channel 4	1427.8979 MHz
Channel 4a (*)	1429.2410 MHz
Channel 5 (**)	1429.4972 MHz
Channel 6 (**)	1431.0965

Parameter	Specification
Upper band edge	1432 MHz
* Available in special geographic area only ** Not available in special geographic areas	

Physical Specifications

ECG-only Transceiver

Parameter	Specification
Height	140 mm
Width	75 mm
Depth	28.5 mm
Weight <ul style="list-style-type: none"> • without batteries or leadset • with batteries and 5-wire leadset 	<ul style="list-style-type: none"> • <165 g (5.8 oz.) • <284 g (10 oz.)
Volume	215 cm ³

Environmental Specifications

ECG/SpO2 Transceiver

Parameter	Specification
Height	140 mm
Width	88 mm
Depth	37 mm
Weight <ul style="list-style-type: none">without batteries or leadsetwith batteries and 5-wire leadset	<ul style="list-style-type: none"><205 g (7.2 oz.)<324 g (11.5 oz.)
Volume	300 cm ³

Environmental Specifications

M4841A Transceiver

Parameter	Specification
Temperature <ul style="list-style-type: none">OperatingStorage	<ul style="list-style-type: none">0 to 37 °C (32 to 99 °F)-40 °C to 60 °C (-40 to 120 °F) without batteries
Humidity <ul style="list-style-type: none">OperatingStorage	<ul style="list-style-type: none">≤ 95% RH at 40 °C (104 °F) non-condensing≤ 90% RH at 60 °C (120 °F) without batteries

Parameter	Specification
Altitude <ul style="list-style-type: none"> Operating & Non-operating 	0 to 3,048 m (10,000 ft)

Measurement Specifications

ECG

Parameter	Specification
ECG channel transmitted Leads <ul style="list-style-type: none"> 3 electrodes 5 electrodes 5 electrodes, EASI 6 electrodes 	<ul style="list-style-type: none"> Channel #1 - I, II, or III Channel #1 - II Channel #2 - III Channel #3 - MCL Channel #1 - Vai Channel #2 - Vas Channel #3 - Ves Channel #1 - II Channel #2 - III Channel #3 - Va Channel #4 - Vb
Resolution	5 μ V
ECG Input	Differential, defibrillator protected against 400 joules discharge into a 50 ohm load
Input Impedance	> 5 megohms (@ 10 Hz)

Measurement Specifications

Parameter	Specification																
Input Dynamic Range	+/- 9 mV																
DC Offset Range	+/- 320 mV																
CMRR	≥ 90 dB @ 50, 60 Hz																
Bandwidth +/- 3 dB	0.05 to 40 Hz																
Gain Accuracy	+/- 5% at 25 °C (77 °F)																
Noise Referred to ECG Input	AAMI: 30 μ V																
Lead Wires	3, 5 or 6-wire leadset. 5-lead compatible with IntelliVue Patient Monitor, AAMI or IEC color code																
Time to baseline from Defibrillator	AAMI: 5 s max (until ECG wave is on display but not yet centered, monitoring bandwidth)																
Pacer Rejection Performance (Pace pulses with no tails)	<p>Positive pacers</p> <table> <thead> <tr> <th><u>Amplitude</u></th> <th><u>Width</u></th> </tr> </thead> <tbody> <tr> <td>+2 to +700 mV</td> <td>0.1, 0.2, 0.5 and 1.0 ms</td> </tr> <tr> <td>+2 to +500 mV</td> <td>1.5 ms</td> </tr> <tr> <td>+2 to +400 mV</td> <td>2 ms</td> </tr> </tbody> </table> <p>Negative pacers</p> <table> <thead> <tr> <th><u>Amplitude</u></th> <th><u>Width</u></th> </tr> </thead> <tbody> <tr> <td>-2 to -700 mV</td> <td>0.1, 0.2, 0.5 and 1.0 ms</td> </tr> <tr> <td>-2 to -500 mV</td> <td>1.5 ms</td> </tr> <tr> <td>-2 to -400 mV</td> <td>2 ms</td> </tr> </tbody> </table>	<u>Amplitude</u>	<u>Width</u>	+2 to +700 mV	0.1, 0.2, 0.5 and 1.0 ms	+2 to +500 mV	1.5 ms	+2 to +400 mV	2 ms	<u>Amplitude</u>	<u>Width</u>	-2 to -700 mV	0.1, 0.2, 0.5 and 1.0 ms	-2 to -500 mV	1.5 ms	-2 to -400 mV	2 ms
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-2 to -400 mV	2 ms																
EMC Performance limits, radiated immunity	46.262 to 55.326 MHz pass at reduced level is 0.4336 V/m. 165 to 195.6 MHz pass at reduced level is 2.4 V/m.																

SpO₂

Parameter	Specification
SpO ₂ Measurement Range	0 to 100%
SpO ₂ Accuracy	<ul style="list-style-type: none"> • +/- 2.5% (1 Standard deviation) with Philips reusable sensor (M1191A, M1192A): 70 - 100 % • +/- 4% (1 Standard deviation) with Philips reusable sensor (M1194A): 70 - 100 % • +/- 3% (1 Standard deviation) with Nellcor Oxisensor D-25 and D-20 sensors: 80 - 100 %
SpO ₂ Resolution	1%
SpO ₂ Numerics - Averaging	10 seconds
SpO ₂ & Pulse Numerics - Update Rate	Transmitted once per second
Pleth Wave - sampling rate	125 sps
Technical Alarms (INOPs)	Triggered if the sensor is disconnected, if a pulse is not detected, if the signal is noisy, if light interference is detected, if the sensor is defective, if the measurement is erratic, or if the module is malfunctioning
Pulse Rate Measurement (available only with Continuous SpO ₂)	Range: 30 to 300 bpm Accuracy: +/- 2% Resolution: 1 bpm

Measurement Specifications

Parameter	Specification
Display of SpO ₂ numerics	SpO ₂ date values are displayed as xxx % SpO ₂ to meet ISO/EN standard EN 865
NIBP INOP suppression feature	If enabled, detection of a NIBP measurement on the same limb and the corresponding suppression of SpO ₂ inops (for max of 60 seconds)

**SpO₂
Sensor
Accuracy**

Type	Description	Model Number	Accuracy% A _{rms} (70-100% Range)
Philips Reusable Sensors	Adult Finger	M1191A	2.0
	Adult Finger	M1191AL	2.0
	Adult Finger	M1191NL	2.0
	Pediatric Finger	M1192A	2.0
	Pediatric Finger	M1192N	2.0
	Adult/Pediatric Ear	M1194A	3.0
	Adult/Pediatric Ear	M1194N	3.0

Measurement Specifications

Type	Description	Model Number	Accuracy% A_{rms} (70-100% Range)
Philips Disposable Sensors	Adult Finger	M1901B	3.0
	Pediatric Finger	M1903B	3.0
	Adult Finger	M1904B	3.0

Measurement Specifications

Type	Description	Model Number	Accuracy% A_{rms} (70-100% Range)
Nellcor Disposable Sensors (not available from Philips)	OxiCliq A, Adult	N/A	3.0
	OxiCliq N, Adult >40 kg (88 lb)	N/A	3.0
	OxiCliq P, Pediatric	N/A	3.0
	OxiMax MAX-A, Adult >30 kg (66 lb)	N/A	3.0
	OxiMax MAX-AL, Adult >30 kg (>66 lb)	N/A	3.0
	OxiMax MAX-N, Adult >40 kg (>88 lb)	N/A	3.0
	OxiMax MAX-P, Pediatric	N/A	3.0
	Oxisensor II D-20, Pediatric 10-50 kg (22-110 lb)	N/A	3.0
	Oxisensor II D-25, Adult >30 kg (>66 lb)	N/A	3.0
	Oxisensor II N-25, Adult >40 kg (>88 lb)	N/A	3.0

A

Accessory List

This appendix lists all accessories that can be used with the transceiver.

For additional information on connecting and using the clinical accessories, see the individual parameter chapters.

Note—Accessories are subject to change. To get the latest accessories, visit the Philips Medical Supplies website located at the following address: <http://shop.medical.philips.com> or your local Philips representative.

Accessory Safety

Warning

Philips's approval: Use only Philips-approved accessories.

Reuse: Never reuse disposable sensors, accessories and so forth that are intended for single use, or single patient use only.

Packaging: Do not use a sterilized accessory if the packaging is damaged.

ECG Accessories

Electrodes

Order Number	Description
M2202A	Radio Translucent Foam Electrodes, 60 packages of 5 (300 per box)
40489E	Paper Tape Electrodes, 10 packages of 30 (300 per box)
40493D	Foam Electrodes, 60 packages of 5 (300 per box)
40493E	Foam Electrodes, 10 packages of 30 (300 per box)

Leadsets

Order Number	Description
9898 031 33831	AAMI 3-wire Leadset, Snap 79 cm (30 ")

Order Number	Description
9898 031 33841	AAM 3-wire Leadset, Grabber 79 cm (30 ")
9898 031 33871	AAMI 5-wire Leadset, Snap 79 cm (30 ")
9898 031 33881	AAMI 5-wire Leadset, Grabber 79 cm (30 ")
9898 031 37241	AAMI 5-wire Color Leadset, Snap 79 cm (30 ")
9898 031 37251	AAMI 5-wire Color Leadset, Grabber 79 cm (30 ")
9898 031 33911	AAMI 6-wire Leadset, Snap 79 cm (30 ")
9898 031 33921	AAMI 6-wire Leadset Grabber 79 cm (30 ")
9898 031 37281	AAMI 6-wire Color Leadset, Snap 79 cm (30 ")
9898 031 37291	AAMI 6-wire Color Leadset, Grabber 79 cm (30 ")

Trunk Cables

Order Number	Description
9898 031 37841	5-lead Trunk Cable

Pouches

Order Number	Description
9898 031 37831	Telemetry Pouch, with flap, box of 50
9898 031 40371	Telemetry Pouch, with flap, case of 200

Skin Prep Paper

Order Number	Description
9898 031 34771	Skin Preparation Sheets, 10 preps/sheet, package of 10 sheets

SpO₂ Accessories

Alignment Guides

Order Number	Description
9898 031 40401	Single Alignment Guide, package of 10
9898 031 40411	Single Tethered Alignment Guide, package of 10
9898 031 40421	Double Alignment Guide, package of 10

Gunk Guards

Order Number	Description
9898 031 40431	ECG Gunk Guard, package of 10
9898 031 40441	SpO ₂ Gunk Guard, package of 10
9898 03140451	Serial SpO ₂ Gunk Guard, package of 10

SpO₂ Accessories

Reusable Sensors

Order Number	Description
M1191A	Philips Adult Finger Sensor, 2 m (6.6 feet)
M1191AL	Philips Adult Finger Sensor, 3 m (9.8 feet)
M1191NL	Philips Adult Finger Sensor, 3 m (9.8 feet)
M1192A	Philips Pediatric Finger Sensor, 1.5 m (4.9 feet)

Order Number	Description
M1192N	Philips Pediatric Finger Sensor, 1.5 m (4.9 feet)
M1194A	Philips Adult & Pediatric Ear Sensor, 1.5 m (4.9 feet)
M1194N	Philips Adult & Pediatric Ear Sensor, 1.5 m (4.9 feet)

Disposable Sensors - Single Use

Note—OxiCliq, OxiMax and Oxisensor II sensors are not available from Philips in the USA or Canada. Adapter cables are not available from Philips in Canada or Japan. In those countries, contact Nellcor Incorporated directly.

Order Number	Description
M1901B	Philips Adult >40 kg (>88 lb)
M1903B	Philips Pediatric 10-50 kg (22-110 lb)
M1904B	Philips Adult >30 kg (>66 lb)
N/A from Philips	*Nellcor Adhesive OxiCliq A, Adult
N/A from Philips	*Nellcor Adhesive OxiCliq N, Adult >40kg (>88 lb)
N/A from Philips	*Nellcor Adhesive OxiCliq P, Pediatric
N/A from Philips	*Nellcor OxiMax MAX-A, Adult >30 kg (>66 lb)
N/A from Philips	*Nellcor OxiMax MAX-AL, Adult >30 kg (>66 lb)
N/A from Philips	*Nellcor OxiMax MAX-N, Adult >40 kg (>88 kg)
N/A from Philips	*Nellcor OxiMax MAX-P, Pediatric 10-50 kg (22-110 lb)
N/A from Philips	*Nellcor Oxisensor II D-20, Pediatric 10-50 kg (22-110 lb)
N/A from Philips	*Nellcor Oxisensor II D-25, Adult >30 kg (>66 lb)
N/A from Philips	*Nellcor Oxisensor II N-25, Adult >40 kg (>88 lb)
M1943A	Adapter cable for Nellcor SpO ₂ sensor, 2 m (6.6 ft)
M1943AL	Adapter cable for Nellcor SpO ₂ sensor, 3 m (9.8 ft)

SpO2 Accessories

Order Number	Description
* Uses reusable OC-3 Sensor Cable.	

Wristband

Order Number	Description
M1627A	Wristband, package of 10

B

Sales and Support Offices

Please call your local sales office listed in your telephone directory or a regional office listed below for the location of your nearest sales office.

CORPORATE HEADQUARTERS:

Philips Medical Systems
Netherlands B.V.
Postbus 10.000
5680 DA Best
Netherlands

UNITED STATES:

Philips Medical Systems
3000 Minuteman Road
Andover, MA 01810
(800) 934-7372

CANADA:

Philips Medical Systems
2660 Matheson Blvd. E.
Mississauga, Ontario L4W 5M2
(800) 291-6743

EUROPE, MIDDLE EAST AND AFRICA:

Philips Medizinsysteme Böblingen GmbH
Cardiac and Monitoring Systems
Hewlett-Packard Str. 2
71034 Böblingen
Germany
Fax: (+49) 7031 463 1552

LATIN AMERICA HEADQUARTERS:

Philips Medical Systems
5200 Blue Lagoon Drive
9th Floor
Miami, FL 33126
(305) 267-4220

ASIA PACIFIC HEADQUARTERS:

Philips Medical Systems
24F Cityplaza One
1111 King's Road
Taikoo Shing, Hong Kong
(+852) 3197 7777

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