Philips Telemetry System

and Telemetry Functions at the IntelliVue Information Center

Notice - for USA only

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

Instructions for Use

Part Number: M2600-92201
Printed in the U.S.A. November 2004
First Edition

PHILIPS

Notice

Instructions for use

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

Printed in the USA.

Document number
M2600-92201

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Printing History

New editions of this document incorporate all material updated since the previous edition. Update packages may be issued between editions and contain replacement and additional pages to be merged by a revision date at the bottom of the page. Pages that are rearranged due to changes on a previous page are not considered revised.

The documentation printing date and part number indicate its current edition. The printing date changes when a new edition is printed. (Minor corrections and updates which are incorporated at reprint do not cause the date to change.) The document part number changes when extensive technical changes are incorporated.

First Edition..... November 2004

Philips Telemetry System, model M2600B is compatible with:

M2604A Philips Mainframe, #01D or #0EU, revision E.00.19
Philips Information Center, revisions F.00, E.01, E.00, D.01, D.00
Philips TeleMon C Companion Monitor
Philips Transmitter, model M2601A

Note—Some features are not available on all products.

About this Book

This book contains operating instructions for use of the M2601B Transmitter, a part of the Philips Telemetry System. 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 the *IntelliVue Information Center Instructions for Use* (order number M3150-9001F). For preventive maintenance, repair, and test methods for verification of device performance, refer to the *M2600B Philips Telemetry System Service and Reference Guide* in the *M2600B Documentation Kit*, shipped with the product (order number M2600-90323).

This book does not address Philips IntelliVue TRx transceivers or the Philips IntelliVue Telemetry System. For information on those products, refer to the manual *Philips IntelliVue Telemetry System Instructions for Use* (order number M4841-91001).

Note—Standard and EASI M2601A Transmitters can be used with the Philips Telemetry System and can operate simultaneously with M2601B Transmitters. “What’s New” on page 1-2 summarizes the differences between the M2601B and M2601A transmitters.

Document Conventions

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:

Click the **Standby** button.

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.

Notes

Note—Notes contain additional information on Philips Telemetry System usage.

Product Safety Information

The warnings below refer to the following devices:

- Philips M2601B Transmitter
- Philips Telemetry System
- IntelliVue Information Center

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.

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 electrosurgery units because use may interrupt or interfere with the transmission of signals from the transmitter.

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. Electrocution could result if these pins are plugged into AC power.

Warning

Use of product accessories (e.g., ECG lead sets, SpO_2 sensors) other than those prescribed by Philips could lead to patient injury.

Warning

Strangulation Hazard! Under no circumstances should any pouch be tied solely around a patient's neck.

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

ECG SAFETY FOR PACED PATIENTS

The output power of the M2601B Transmitter 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 transmitter 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 Telemetry System. See the *IntelliVue Information Center Instructions for Use* for additional information on monitoring paced patients.

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.

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 alerts 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.

Contents

1
Introduction to the Philips Telemetry System

This chapter introduces the Philips Telemetry System. It includes the following sections:

What's New

This section highlights the differences between the M2600B Philips Telemetry System, utilizing the M2601B Transmitter and the Philips M2600A Telemetry System, Release C, utilizing the M2601A Transmitter.

New Transmitter

The main difference between the two systems is the introduction of the new M2601B transmitter.

Differences Between Transmitters

The following table summarizes the differences between the two transmitters.

	M2601B	**M2601A**
Function	One transmitter for both Standard and EASI monitoring -- clinician simply changes the ECG lead set position	Separate Standard or EASI versions of transmitter
	FAST (Fourier Artifact Suppression Technology) SpO_2 algorithm	Traditional (not motion tolerant) SpO_2 algorithm
	Continuous and Spot Check (Manual) SpO_2 measurements	Continuous, Spot Check (Manual), and Intermittent (1- and 5-minute) SpO_2 measurements

	M2601B	**M2601A**
Controls & Indicators	Spot Check SpO_2 initiated by inserting sensor cable	Manual measurement initiated by button push on transmitter
	Auditory feedback for Spot Check and self test	N/A
	Two electrode placement diagrams show *both* Standard *and* EASI placement	One electrode placement diagram appropriate for the transmitter: *either* Standard *or* EASI placement
	Check button for verifying transmitter status: lead set type, battery level, EASI indicator (if in use)	N/A
	Battery gauge to indicate power level	N/A
	Audible volume/mute configurations	N/A
	Audible pulse detection during Spot Check measurement	N/A
	Unit designator label on battery compartment	N/A
Physical	Smaller and lighter ECG-only transmitter ECG/SpO_2 transmitter approximately same size as the M2601A	One-size transmitter (ECG-only or ECG/SpO_2)
Power Source	Battery Type: 2 AA Alkaline	Battery Types: 1 9-volt Alkaline, Lithium, Zinc Air
	No support for Battery Extender	Compatible with Battery Extender
Accessories	New 5-wire lead sets, with color-coded lead wires available	N/A

Connection to TeleMon

The M2601B Transmitter also has a different method of connecting to the TeleMon C Companion Monitor:

- M2601B: Transmitter is connected to the outside of TeleMon via a 3-meter Interconnect cable.
- M2601A: Transmitter is docked in TeleMon.

Telemetry Overview

The system supports Telemetry Overview, the pairing of a telemetry bed and an IntelliVue Patient Monitor (Release B.1 or higher) for a single patient. Telemetry Overview provides the telemetry-monitor data (waveforms, parameters, and alarms) in an integrated form both on the bedside monitor and at the IntelliVue Information Center.

Telemetry Overview is available with both the M2601B and M2601A transmitters.

Information on Telemetry Overview can be found in the *IntelliVue Patient Monitor Instructions for Use* and the *IntelliVue Information Center Instructions for Use*. In this book, "Alarm Behavior with Telemetry Overview" on page 2-3 summarizes alarm functionality with Telemetry Overview.

Indications for Use

The paragraphs below are the elements of the indications for use statement for the Philips Telemetry System.

Condition

The licensed clinician decides that the Philips Telemetry System should be used to monitor the patient.

Prescription Versus Over-the-Counter

The Philips Telemetry System is a prescription device.

Part of the Body or Type of Tissue with which the Device Interacts

The ECG signal is obtained from accessory electrodes in contact with the patient's skin. The SpO_2 signal is obtained from an accessory sensor in contact with the patient's skin.

Frequency of Use

As prescribed by a licensed physician.

Physiological Purpose

To monitor the ECG and SpO_2 of patients on the order of a licensed physician.

Patient Population

Adult and pediatric patients.

Intended Use

The Philips Telemetry System is a comprehensive ambulatory system solution for the intermediate care unit for adult and pediatric patients. The foundation of the system is a transmitter that can capture and transmit ECG signals and SpO_2 values (if available) that are then processed and displayed on the IntelliVue Information Center. The Information Center generates alarms and recordings, thus notifying clinicians of changes in patients' conditions. The Telemetry System communicates with other devices via the Philips patient care system.

Warning

United States law restricts this device to sale by or on the order of a physician. This product is intended for use in health care facilities by trained health care professionals. It is not intended for home use.

Regulatory Information

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

The transmitter 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.

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

The system is not intended to be connected to public mains as defined in CISPR 11.

System Overview

The Philips Telemetry System is used with the IntelliVue Information Center to provide multi-parameter measurements for transitional care and other ambulatory monitoring environments for adult and pediatric patients. The system:

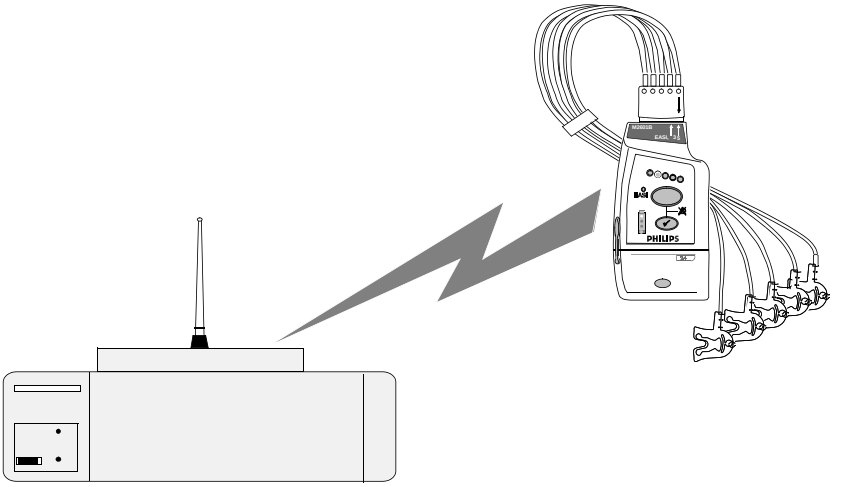
- Enunciates patient monitoring alarms.
- Monitors adult and pediatric patients' ECG.
- Provides ST/AR arrhythmia detection.
- Measures pulsatile arterial oxygen saturation (SpO_2) and pulse rate, if available.
- Enables viewing of ECG and SpO_2 measurements and waveforms at the patient's side when connected to the Philips TeleMon C Companion Monitor.
- Makes ST segment measurements.

The Philips Telemetry System consists of:

- A transmitter for each patient.
- An antenna system.
- A receiver for each transmitter.
- A mainframe housing up to eight receivers.

Other possible items include:

- The TeleMon Companion Monitor: TeleMon can be used to view waveforms and heart rate and SpO_2 numerics as well as measure NBP. For more information see the *Philips TeleMon C Companion Monitor Instructions for Use*.



Philips Telemetry System

Dual-Band Operation

The Philips Telemetry System (M2600B) can operate in both the 406-480 MHz and 590-614 MHz ranges. The exact operating frequency for each transmitter/receiver pair is set so as to meet specific customer needs, while maintaining compliance with local and international radio regulations.

For United States operation, the M2600B will operate only in the protected, dedicated Wireless Medical Telemetry Service (WMTS) band (608-614 MHz).

Transmitters

The following Philips transmitters can be used with the Philips Telemetry System:

- ECG-only transmitter
- ECG/SpO_2 transmitter

Standard and EASI M2601A transmitters can also be used. These transmitters can operate simultaneously with M2601B transmitters. For operating information, refer to the *Instructions for Use* for the Philips Telemetry System (part number M2600-9001C).

> *Note*—"What's New" on page 1-2 summarizes the differences between the M2601B and M2601A transmitters.

The M2601B Transmitter models are illustrated on the following pages in this chapter. Subsequent tables describe the controls, indicators, markings, and audible sounds respectively.

If your hospital uses both the M2601B Transmitter and IntelliVue TRx devices
The M2601B Transmitter and M4841A TRx Transceiver are similar in appearance. You can distinguish between them by: • Name on the front of the device • Label color (dark gray for M2601B and pale gray for TRx)

M2601B Transmitter Features

- Clinician-selectable Standard or EASI leads in same transmitter, at the bedside.
- Powered by two AA Alkaline batteries.
- Spot Check SpO_2 without using any control buttons.
- FAST-SpO_2 (Fourier Artifact Suppression Technology) for improved motion artifact rejection and low-perfusion performance.
- Simultaneous operation in system with M2601A Transmitter.
- Two sizes - smaller ECG-only version and larger ECG-SpO_2 version.
- Battery gauge on transmitter.
- Designed to be ergonomic and comfortable for patients to wear.
- Colored labels provide clinical unit identifiers.
- Lead sets are optimized for ambulating patients, with a cable length of 79 cm (30 in).
- Protective covers prevent dirt from accessing unused ECG and SpO_2 cable ports and the unused TeleMon/Service port, thus simplifying cleaning.
- New pouches with clear front and flap.

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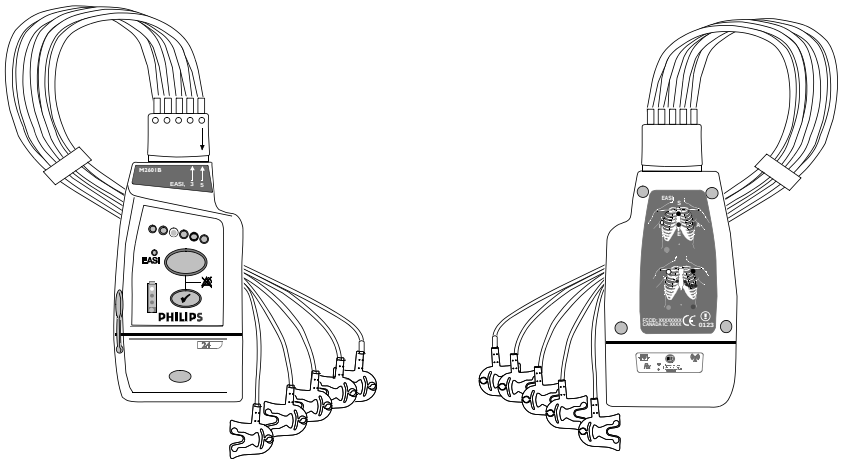
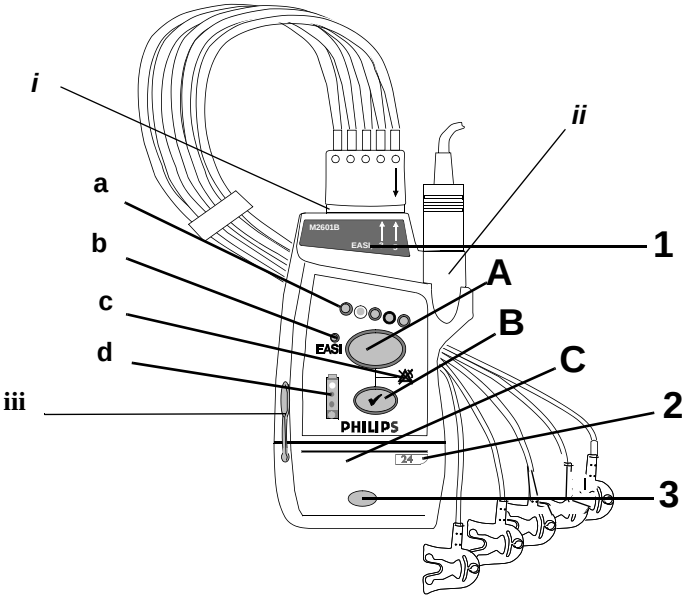


Front View **Back View**

M2601B Transmitter - ECG only

Transmitter Controls - Front



ECG/SpO_2 Transmitter - Front View

The labeled items in the diagram above include:

- Transmitter controls (A-C)
- Indicators (a-d)
- Labels (1-3)
- Ports (i-iii)

These items are defined on subsequent tables.

Controls

Callout	Control	Definition
A		**Telemetry Button**: Depending on the configuration, this multi-function button directs the Information Center to generate a Nurse Call, central recording, both, or none. If desired, you can turn Nurse Call off for individual patients at the Information Center by using the Telemetry Setup Window. See "Turning Nurse Call On/Off" on page 1-23 for additional information. *Note*—Recordings generated by the telemetry button are stored in Alarm Review at the Information Center. *Note*—If the installation includes a paging system and if the Information Center is configured for paging upon receipt of Nurse Call, a Nurse Page signal will be initiated.
B		**Check Button**. Checks the status of the transmitter. When pressed, the battery gauge, lead set type, and EASI (if in use) indicators illuminate.
C	**Power On/Off**	**Battery Compartment**. Battery insertion turns power on; battery removal turns power off.

Indicators

Callout	Indicator	Definition
a		**Lead Indicator**. • Lights momentarily to display leads attached when lead set is inserted or when the Check button is pressed. • When a Leads Off condition occurs, the light(s) indicate the lead(s) that need to be reapplied. The light(s) remain on until the Leads Off condition ends. *Note*—The 6th indicator (left-most LED) is not used for the M2601B Transmitter.
b		**EASI Indicator**. Illuminates momentarily upon insertion of lead set in EASI position. Lit by Check button when EASI is in use.
c		**Alarms Pause/Suspend Indicator**. Inactive. *Note*—If the transmitter is connected to TeleMon this indicator is lit during 3 minute alarm pause period initiated at TeleMon.
d		**Battery Gauge**. When the Check button is pressed, indicates the amount of power remaining in the batteries. Valid only for recommended battery type. *Note*—See “Checking the Battery Power Level” on page 1-32.

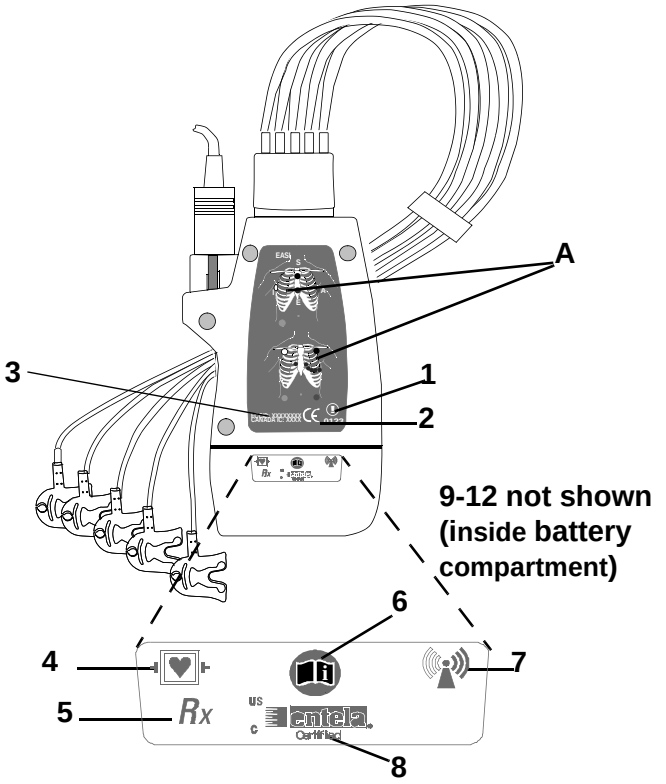
Front Labels

Callout	Label	Definition
1		**Lead Set Insertion Guide**. See "Connecting the ECG Cable" on page 3-14.
2		**Device Identification Label**
3		**Unit Identification Label.** (one of seven colors). Color-coded sticker.

Ports

Callout	Definition
i	**ECG Lead Set Port**. Connection for 3-wire or 5-wire lead set.
ii	**SpO_2 Sensor Port**. Connection for SpO_2 sensor.
iii	**TeleMon/Service Port.** Connection for cable to TeleMon or to Service Tool.

Transmitter Controls - Back



ECG/SpO$_2$ Transmitter - Back View

The labeled items in the diagram above include:

- Labels (A)
- Safety symbols and other markings (1-12)

These items are defined on subsequent tables.

Back Labels

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

Safety Symbols and Other Markings

Callout	Label	Definition
1		Considered Class 2 radio equipment per Directive 1999/5/EC for which Member States may apply restrictions on putting the device into service or placing it on the market. This device is intended to be connected to the publicly available interfaces (PAI) for use throughout the EEA.
2		Compliance to Council Directive 93/42/EEC (MDD).
3	**FCCID: XXXXXXXX** **CANADA IC: XXXX**	FCC and Canadian license labels.
4		The transmitter patient connections are protected against defibrillation (DEFIBRILLATION-PROOF) and are a TYPE CF APPLIED PART.
5	***Rx***	Prescription device.

Callout	Label	Definition
6		Follow operating instructions.
7		Non-Ionizing Radiation. Interference to electronic equipment may occur in the vicinity of devices marked with this symbol.
8		Complies with all applicable Canadian and American standards.
9	SN	Serial Number. Needed to identify the equipment during a call to the Response Center.
10	REF	Philips Catalog Number.
11	MAC	MAC Address of device. Used for upgrade.
12		Date of manufacture.

Sounds

The transmitter produces auditory information signals to inform you of measurement and battery conditions. The main tone, which can be set to one of 5 different volume settings or turned off, is configurable. In addition, a lower pitched tone is used to identify a pulse beat occurring during an SpO_2 Spot Check measurement.

Auditory Information Signal	Definition
Beep	Power On Self Test Passed SpO_2 Spot Check Measurement Complete
Beep Beep	Power On Self Test Failed SpO_2 Spot Check Measurement Failed
Boop	Boop signal corresponding to detected Pulse (during SpO_2 Spot Check measurement only)
Alternating Pitch Repeated Tone	Check code configured in transmitter does not match the expected check code of the Service Tool

Transmitter Safety Information

Warning

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

Warning

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

Warning

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

Briefing the Patient

Warning

Patients should be instructed not to open the battery compartment while the transmitter is in use.

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

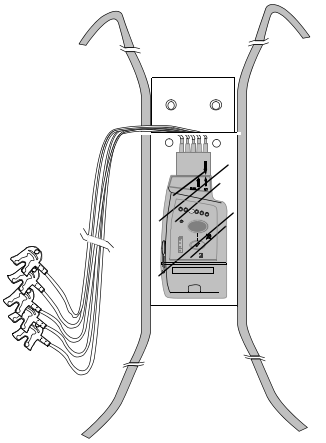
Note—If desired, the clinician can turn off patient use of the button. See "Turning Nurse Call On/Off" on page 1-23.

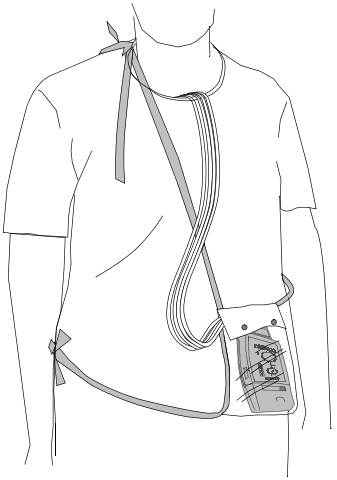
Pouch Use

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

Securing the Pouch

Task Summary

Step	Action
1	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. **Warning** **To avoid strangulation, do not tie a pouch solely around the patient's neck.**
2	Insert the transmitter into the pouch with lead wires and SpO2 sensor cable, if used, exiting from the same side.  *Important*—Do not coil the cables inside the pouch. They are part of the antenna system and need to be freely exposed.

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

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 transmitter 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 transmitter and pouch will withstand showering for up to 10 minutes.

Drying the Transmitter after Showering

After showering, perform the following steps to continue monitoring:

1. Pat dry the lead set connections at the electrodes.
2. Wipe the lead wires with care.
3. If wet, dry the outside of the transmitter 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 transmitter 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 transmitter 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/EO sterilization under “Transmitter Cleaning and Ethylene Oxide (EO) Sterilization” on page 6-4 as appropriate.

Making Monitoring Adjustments

Turning the Transmitter On/Off

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

Note—Transmitter settings (SpO2 mode, audible tone volume, etc.) set using the Service Tool/TeleMon are retained indefinitely after battery removal.

Warning

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

Turning Telemetry Monitoring On/Off

Telemetry monitoring can be turned on or off in one of two ways:

- Manually, by activating Monitoring Standby at the IntelliVue Information Center (see “Standby Mode” on page 1-24).
- Automatically, if Auto Shutoff is enabled at the transmitter and if all leads are off for 10 minutes (see “Transmitter Auto Shutoff” on page 1-23).

Note—Turning telemetry monitoring off *does not turn the transmitter off*. Turn the transmitter off by removing the batteries.

Transmitter Auto Shutoff

A service feature of the transmitter is RF Automatic Shutoff, which causes the transmitter to stop broadcasting a radio signal if all leads are off for 10 minutes. This prevents interference with other transmitters in use. The technical alarm message at the Information Center is TRANSMITTER OFF. To restart monitoring, attach leads to the patient. Automatic Shutoff can be configured off. Batteries must be removed when the transmitters are not in use to prevent RF interference and unnecessary battery drain.

> *Note*—Automatic Shutoff does not save battery life. In order to allow an automatic turn-on when the leads are reattached, transmitter functions are not completely disabled in this mode. To extend battery life, remove the batteries when the transmitter is not in use.

Turning Nurse Call On/Off

If the Telemetry button on the transmitter is configured for a Nurse Call alarm, you can inhibit the alarm for individual patients by using the Telemetry Setup Window on the Information Center. If your system is configured for both a Nurse Call alarm and a recording, only the Nurse Call alarm is inhibited by turning it off: recordings are still made.

Task Summary

Turn the Telemetry button on the transmitter on or off by performing the following steps:

Step	Action
1	On the Patient Window click the **All Controls** button.

Step	Action
2	On the All Controls Window click **Telemetry Setup**.
3	On the Telemetry Setup Window turn the Telemetry button on or off by clicking in the **Telemetry Button Allow Calls** checkbox. A check mark in the checkbox indicates that the Telemetry button is on.

Standby Mode

When a patient is temporarily off the unit or out of antenna range you can suspend monitoring by placing telemetry in Standby mode. Standby suspends monitoring, and you won't get any waveforms or alarms.

Note—If you remove the leads before putting a patient into Standby, you'll get a LEADS OFF technical alarm, and reminders if configured.

Warning

If you put telemetry in Standby mode, you *must* remember to turn monitoring back on when the patient returns to the unit.

Note—When you take an EASI transmitter out of Standby, the lead settings revert back to the central's default lead settings (i.e., II and V2).

Task Summary

Place a patient in Standby by performing the following steps:

Step	Action
1	On the Patient Window click the **Standby** button.
2	Select the patient's location from the pre-defined list.

Step	Action
3	Click the **Suspend Monitoring** button. This suspends all monitoring and displays the following message in the Patient Sector TELEMETRY STANDBY and the location (for example, X-Ray). *Note*—Be sure to take the bed out of Standby before discharging. Since Standby is associated with the equipment assigned to a bed, if a patient is discharged and the bed is in Standby mode, that equipment will be in Standby for the next patient, and monitoring will continue to be interrupted.
4	When the patient comes back, restart monitoring by clicking on **Resume Monitoring** in the Patient Sector.

Use with TeleMon C

The M2601B Transmitter can employ the full functionality of the Philips TeleMon C Companion Monitor, including NBP measurement and local display of alarms. Connection is made through an interface cable at the TeleMon/ Service port. Please refer to the *Philips TeleMon C Companion Monitor Instructions for Use* for operating instructions.

Note—Batteries with adequate life remaining should be inserted in the transmitter before connecting to TeleMon. Press the Check button to find the battery life status. If the batteries are in a BATTERY WEAK state (1 red indicator), they should be replaced before connection.

Operation with TeleMon

When the transmitter is connected to TeleMon:

- Standby mode is not available.
- 3-minute alarm pause/suspend is available from TeleMon. The alarm pause indicator on the transmitter will accurately reflect the current state of alarm pause at TeleMon.

- After a change in lead set, TeleMon returns to the default ECG settings, and arrhythmia relearn occurs automatically. Be sure to check the monitoring leads after you switch lead sets.
- Arrhythmia relearn will occur at TeleMon automatically if the lead set is changed.
- When the Check button is pressed, the transmitter battery gauge indicates full regardless of battery state.
- The transmitter receives operating power from TeleMon when connected/docked.
  Note—Batteries are not being charged when the transmitter is connected/docked.

For information on SpO_2 operation, see "SpO_2Measurement when Connected to TeleMon" on page 5-17.

Testing the Transmitter Functionality

There are two tests of the transmitter functionality:

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

Self Test

Warning

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

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

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

In Case of Failure

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

Status Check

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

Task Summary

To initiate a Status Check, use the following instructions.

Step	Action
1	Press the **Check** button.
2	The following indicators should illuminate for as long as the Check button is depressed. • Battery gauge • Type of lead set • EASI (if in use)
3	If one or more of the expected indicators do not light up, check the following: • Make sure the lead set block is correctly inserted in the transmitter and the yellow line at the base of the cable is not visible (see “Connecting the ECG Cable” on page 3-14) • Power and position of batteries (see “Checking the Battery Power Level” on page 1-32) • Lead positions and connections (see “Verifying Electrode Connections” on page 3-17)
4	If there is still a problem, contact your Service Provider for assistance.

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-Weak warning time). The use of fresh high-quality alkaline batteries is strongly recommended.

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

If battery leakage should occur, use caution in removing the batteries. The leaked substance may cause eye or skin irritation. Avoid contact with skin. Clean the battery compartment according to instructions in "Chapter 6. Maintenance and Configuration". 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 transmitter becomes hot to the touch, place it aside until it cools. Then remove the batteries and discard them. Have the transmitter 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 WEAK alarm, the batteries must be promptly replaced. A "Battery Weak" condition that is not corrected will result in transmitter shutdown and cessation of monitoring.

Disposal of Batteries

Caution

Batteries must be removed if a transmitter 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 regulations.

Battery Life

Battery life is dependent upon:

- Condition of the batteries.
- Parameters being monitored - ECG only, ECG and Spot Check SpO_2, or ECG and Continuous SpO_2.

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

- REMOVE THE BATTERIES when the transmitter is not in use.
- If using TeleMon, see the *Philips TeleMon C Companion Monitor Instructions for Use*.

  Note—Automatic Shutoff of the transmitter does not eliminate battery usage. In order to allow an automatic turn-on, the transmitter ECG and SpO_2 functions are not completely disabled in this mode.

Note—The Battery Extender for the M2601A Transmitter **cannot** be used with the M2601B Transmitter to extend battery life.

Inserting/ Removing Batteries

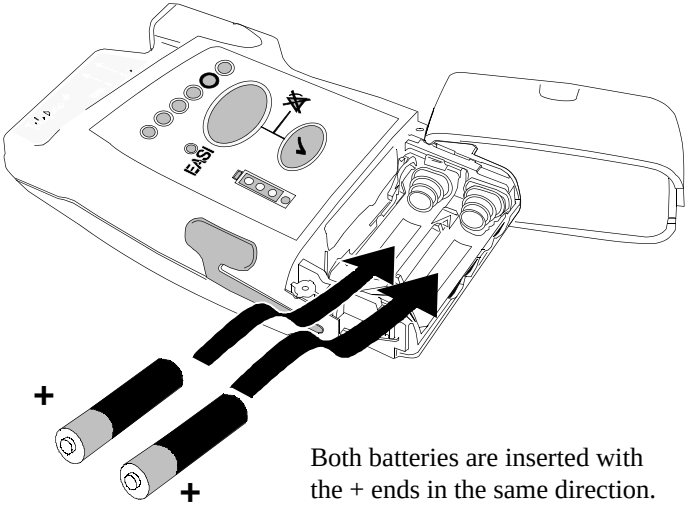
The battery compartment is located at the bottom of the transmitter and accommodates a pair of AA 1.5V Alkaline batteries. Only this type of disposable battery shall be used.

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

- Battery gauge performance.
- Battery weak warnings.
- Battery life performance.

Task Summary

Insert batteries into the transmitter using the following procedure.

Step	Action
1	Open battery compartment by swinging the compartment door 90^{o} into an open hinged position.
2	Insert two disposable AA 1.5V Alkaline batteries, matching the polarity with the +/- indications inside the compartment.  Both batteries are inserted with the + ends in the same direction.
3	Close the battery compartment door.

Warning

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

Batteries should be changed in sets, that is, if you change one battery, change them both.

If you remove good batteries to turn off the transmitter, 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 transmitter is not in use or is being stored. DO NOT STORE BATTERIES BY LEAVING THEM IN THE INCORRECT POLARITY POSITION INSIDE THE TRANSMITTER.

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 transmitter indicates the battery power level.

The approximate battery life remaining indicated by the gauge is given in the table below. The percentages and times are for ECG operation only.

Note—The battery life times are based on Duracell MN 1500 batteries. Battery life for other brands may be different.

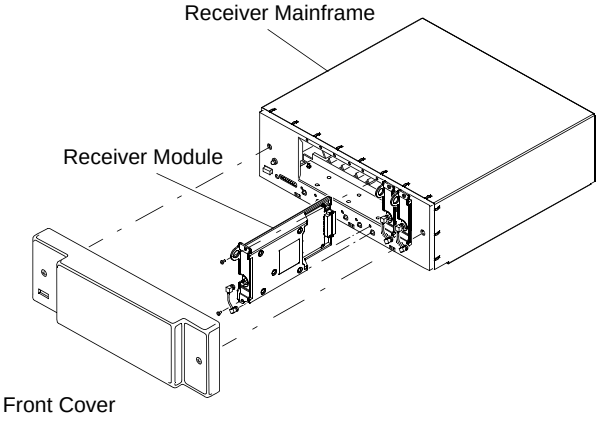
Battery Gauge	Approximate Battery Life Remaining (ECG Only)	Approximate Operating Time Remaining	Functionality
4 green indicators	>75%	>30.4 hours Japanese version: >33 hours	Normal operation
3 green indicators	>50%	>20.3 hours Japanese version: >22 hours	Normal operation
2 green indicators	>25%	>10.1 hours Japanese version: >11 hours	Normal operation
1 green indicator	25% to BATTERY WEAK level	>15 minutes	Normal operation
1 red indicator	BATTERY WEAK level to REPLACE BATTERY level	<15 minutes	SpO_2 disabled
no indicator	REPLACE BATTERY level (Check batteries for correct polarity)		Transmitter shutdown

Task Summary To check the power level, use the following instructions.

Step	Action
1	Insert batteries if the transmitter is not already on.
2	Press the **Check** button to determine the level. (See “Checking the Battery Power Level” on page 1-32.):
3	**If no indicators flash:** 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. **If the indicators illuminate but do not behave** as described above, the transmitter has malfunctioned. Contact your Service Provider.

Receiver Module

The Philips receiver modules are housed in the receiver mainframe. Each receiver module is dedicated to a specific transmitter by an internal identity code. This prevents another patient's waveform from being erroneously transmitted and displayed. The receiver acquires the ECG and SpO_2 signals from the transmitter and sends them to the receiver mainframe.



Receiver Mainframe

The Philips receiver mainframe houses up to eight receiver modules. For each receiver, the receiver mainframe calculates the heart rate, and sends the waveform, patient alarms, technical alarms, and status messages over the Philips patient care system to the IntelliVue Information Center for display and recording. If SpO_2 is available, the transmitter processes the data and sends it to the IntelliVue Information Center via the network as well.

Turning the Receiver Mainframe On or Off

The receiver mainframe must be turned on for individual transmitters and receivers to work. To turn the receiver mainframe on, the power cord must be attached and connected to an AC outlet. A green LED on the rear of the Mainframe will light then.

If the receiver mainframe is turned off, the light and all receiver modules are off.

Receiver Mainframe Malfunction Light

A red light on the front panel of the mainframe illuminates when either the mainframe or one of the receivers has malfunctioned. Depending on the problem, you may see the message, NO DATA FROM BED or RECEIVER MALF, in single or multiple patient sectors. Contact your Service Provider.

When the mainframe is first turned on, the red light flashes. If no problems are detected, the flashing stops and the light turns off.

Channel Frequencies

The frequency of Philips transmitters and receivers are programmable, thus enabling changes in frequency if interference is detected. In case of interference, contact service.

Retaining Telemetry Settings

If power to the receiver mainframe is interrupted or turned off, settings controlled by the mainframe such as leads may be affected.

- If the receiver mainframe is turned off for less than three hours, your settings should still be in effect.
- If the mainframe is turned off for more than three hours, your settings revert to default, that is, to the configured settings at installation.

Antenna System

The telemetry antenna system is custom-designed for your unit to ensure adequate coverage, therefore the telemetry signal can only be received where there are receiving antennas. After it is received by the antenna system, it is sent to the receiver which recovers the patient's ECG and optional SpO_2. This information is then sent to a monitoring display.

2
Alarms

This chapter describes alarm behavior and lists Physiologic Alarms (Patient Alarms) and Technical Alarms (Inoperative Conditions). Both types of alarms are listed alphabetically.

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 Online Help. The Information Center documentation also includes the default alarm settings and physiological alarm limit ranges.

Pause/Suspend Alarms

All alarms for a patient can be paused/suspended from the Information Center, or from the Philips TeleMon C Companion Monitor, if connected. See the *Instructions for Use* for the Information Center or TeleMon for directions.

If connected to TeleMon, alarms can be suspended only from TeleMon, and not from the Information Center. If alarms are suspended from TeleMon, the Alarms Suspend icon on the transmitter is lit (see “Transmitter Controls - Front” on page 1-11) and an ALARMS SUSPENDED message appears at TeleMon and the Information Center.

Alarm Behavior with Telemetry Overview

Both the IntelliVue Patient Monitor and the telemetry system source alarms. The following tables summarize alarm behavior when Telemetry 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.

Warning

If the remote Silence key in the Overview window is enabled for IntelliVue monitors connected to the Information Center, remote silencing for these beds may be enabled in other clinical units.

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 and/or telemetry alarm are silenced	Bedside alarm is silenced (if Silence Overview Alarms is configured at the Information Center)
Bedside and/or telemetry alarm	Information Center	Bedside or telemetry alarm is silenced	Bedside or telemetry alarm is silenced

Note—If connected 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 *Note*—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 (Patient) Alarms

There are no physiologic (patient) alarm signals generated by the transmitter. **All physiologic alarms are generated at the IntelliVue Information Center, and all alarm signals must be acknowledged at the Information Center.**

Note—When Telemetry Overview is used, alarms can also be acknowledged at the bedside (see “Alarm Silence” on page 2-4).

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*.

If arrhythmia is turned off at the Information Center, the cardiotach is available on the telemetry mainframe for the following alarms: Asystole, V-fib, High HR, Low HR.

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

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

Note—In Release D.00/D.01/E.00/E.01 of the IntelliVue Information Center, yellow ST/AR arrhythmia alarms are indicated by (**) rather than (*). Also, text of some alarm messages depends on the release of the Information Center.

Physiologic (Patient) Alarms

Alarm Text	Priority	Condition	Source
***ASYSTOLE	Red	Asystole. No QRS for 4 consecutive seconds	ST/AR Basic and Enhanced Arrhythmia Mainframe cardiotach
*** BRADY yyy <xxx or *** EXTREME BRADY	Red	Extreme Bradycardia. HR < extreme Brady HR Limit	ST/AR Basic and Enhanced Arrhythmia
*** TACHY yyy < xxx or *** EXTREME TACHY	Red	Extreme Tachycardia. HR > extreme Tachy HR Limit	ST/AR Basic and Enhanced Arrhythmia
*** VENT FIB	Red	Ventricular Fibrillation. Fibrillatory waveform for 4 consecutive seconds	Mainframe cardiotach
*** V-FIB/TACH	Red	Ventricular Fibrillation. Fibrillatory waveform for 4 consecutive seconds	ST/AR Basic and Enhanced Arrhythmia
*** V-TACH	Red	Ventricular Tachycardia. Sustained run of PVCs accompanied by a high heart rate	ST/AR Basic and Enhanced Arrhythmia
**HR yyy > xxx	Yellow	High Heart Rate. HR > high HR Limit	Mainframe cardiotach
**HR yyy < xxx	Yellow	Low Heart Rate. HR < low HR Limit	Mainframe cardiotach

Physiologic (Patient) Alarms

Alarm Text	Priority	Condition	Source
** NURSE CALL	Yellow	Telemetry button press on the transmitter (when configured for Nurse Call operation)	Clinician/patient-initiated at the transmitter
** SpO2 yyy > xxx or ** SpO2T yyy > xxx	Yellow	High SpO_2. SpO_2 value greater than high SpO_2 Limit	SpO_2
** SpO2 yyy < xxx or ** SpO2T yyy < xxx	Yellow	Low SpO_2. SpO_2 value less than low SpO_2 Limit	SpO_2
* HR yyy > xxx or * HIGH HR	Yellow	High Heart Rate. HR > high HR Limit	ST/AR Basic and Enhanced Arrhythmia
* HR yyy < xxx or * LOW HR	Yellow	Low Heart Rate. HR < low HR Limit	ST/AR Basic and 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 Ld X, Ld Y	Yellow	Multi ST Leads exceeding Limit (EASI mode or when selected). Two ST leads (Ld X, Ld Y) exceed elevation or depression for > 60 seconds	ST/AR Arrhythmia
* MULTIFORM PVCs	Yellow	Multiform PVCs	ST/AR Enhanced Arrhythmia

Physiologic (Patient) Alarms

Alarm Text	Priority	Condition	Source
* 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 and Enhanced Arrhythmia
* PACER NOT PACE	Yellow	Pacer Not Pacing. Missed beat without pace pulse (paced patient).	ST/AR Basic and Enhanced Arrhythmia
* PAIR PVCs	Yellow	Pair of PVCs.	ST/AR Enhanced Arrhythmia
* PAUSE	Yellow	Pause. No QRS for > x seconds	ST/AR Enhanced Arrhythmia
* PVC > xx/min	Yellow	PVCs > xx/min. PVCs > Rate Limit	ST/AR Basic and 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

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

Technical Alarms (INOPs)

Technical alarms, or INOPs, are sourced at the transmitter, the mainframe, or the ST/AR algorithm running at the Information Center, and identify inoperative conditions. There are two types of technical alarms. A *Hard* technical alarm indicates that monitoring and alarms are disabled and generates an audible tone at the Information Center. With a *Soft* technical alarm, monitoring and alarms remain active, and no audible tone is generated.

Technical Alarms (INOPs)

Alarm Text	Priority	Condition	What to do
##nnn/nnn(nnn)nnn (RF technical alarm)	Soft	Used by service in troubleshooting the radio signal	Contact Service Provider.
ARRHY REQUIRED	Hard	Arrhythmia monitoring was turned off for an EASI transmitter.	Turn arrhythmia monitoring on or move lead set to the Standard ECG position if arrhythmia monitoring is not desired.
BATTERY WEAK	Soft	Weak batteries	Replace batteries promptly to avoid transmitter 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. *Note*—See "Optimizing System Performance" on page 3-21.
CANNOT ANALYZE ST	Soft	ST algorithm cannot reliably generate any valid ST values on any monitored lead.	Assess the lead selections. *Note*—See "Optimizing System Performance" on page 3-21.

Technical Alarms (INOPs)

Alarm Text	Priority	Condition	What to do
ECG EQUIP MALF	Hard	Failure of the ECG equipment or failure to calibrate ECG	Replace transmitter. Contact Service.
INTERFERENCE	Hard	Interference due to outside source	Check that there are no transmitters stored with batteries inserted. Change the Philips transmitter and receiver frequency. Contact Service Provider.
INVALID LEADSET	Hard	Bad lead selection switches in transmitter	Use supported lead set. Contact Service.
INVALID SIGNAL E01	Hard	Receiver is picking up a duplicate frequency.	When the transmitter is not being used, turn telemetry monitoring off for the bed. If the situation continues, contact Service. If this is a new transmitter, the system must learn the new transmitter ID code - contact Service Provider.
LEADS OFF	Hard	Single or multiple leads off	Reattach ECG leads to patient.
NO RECEIVER	Hard	Receiver absent or malfunctioning	This message appears after the mainframe is turned on and indicates the absence of a receiver or a receiver is faulty. Contact Service Provider.

Technical Alarms (INOPs)

Alarm Text	Priority	Condition	What to do
NO SIGNAL	Hard	Patient is out of range, radio board has failed, no batteries in transmitter, or batteries inserted incorrectly.	Make sure that the transmitter is in range. Check batteries for correct insertion. Replace transmitter if Power On Self Test fails, and notify Service Provider.
RECEIVER MALF	Hard	Receiver is malfunctioning.	Contact Service Provider.
REPLACE BATTERY	Hard, Latched Message remains until acknowledged by clinician.	Batteries are unable to power the transmitter, or batteries are inserted backwards. No monitoring is occurring.	Replace batteries/check batteries for correct insertion.
SpO2 EQUIP MALF	Hard	Malfunction in the SpO_2 hardware	SpO_2 board needs to be replaced. Call Service Provider.
SpO2 ERRATIC	Hard	Erratic SpO_2 measurements, often due to a faulty sensor or invalid SpO_2 measurements, or incorrect sensor position	Repeat measurement, reposition sensor on patient, or finally, replace sensor.
SpO2 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. Conceal/cover sensor with opaque non-white cover.
SpO2 NO TRANSDUCER	Hard	No sensor attached to SpO_2 device	Attach SpO_2 sensor.

Technical Alarms (INOPs)

Alarm Text	Priority	Condition	What to do
SpO2 NOISY SIGNAL	Hard	Excessive patient movements or electrical interference are causing irregular pulse patterns	Reduce movement or electrical noise sources.
SpO2 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.
SpO2 TRANS MALF	Hard	Malfunction of the SpO_2 sensor/adapter-cable	Replace sensor.
TEL CANNOT ANALYZE	Hard	Shorts bursts of data corruption inhibiting an accurate HR count. (Often accompanied by WEAK SIGNAL, NO SIGNAL, or INTERFERENCE INOPs.)	Check that there are no transmitters stored with batteries. Check to see if the patient is in the coverage area, and return patient if needed. If the patient is in the coverage area and is stationary, move the transmitter or patient about 6 inches (15 cm.). If the situation persists, contact Service Provider.
TRANSMITTER MALF	Hard	Transmitter malfunction	Replace transmitter and notify Service Provider.

Technical Alarms (INOPs)

Alarm Text	Priority	Condition	What to do
TRANSMITTER OFF	Soft	RF shut off after 10 minutes of leads off	Reattach ECG leads to patient.
WEAK SIGNAL	Soft	Weak RF signal received at Telemetry Mainframe from transmitter	Move transmitter into RF coverage area and re-check transmitter. If condition exists in close proximity to the antenna, replace transmitter. Check to see if the patient is in the coverage area, and return patient if needed. If the patient is in the coverage area and is stationary, move the transmitter or patient about 6 inches (15 cm.). If the situation persists, contact Service Provider.

3
ECG & ST/AR Measurement

This chapter covers the specifics of ECG measurement, as well as arrhythmia monitoring using the ST/AR algorithm. It includes the following sections:

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 cardiotach within the transmitter: cardiotach analysis resides in the telemetry mainframe. The type of ECG analysis depends on whether or not arrhythmia analysis is on or off at the Information Center.

- When arrhythmia is turned *on* at the Information Center, the cardiotach is included as part of arrhythmia analysis in the Information Center for standard lead placement.
- When arrhythmia is turned *off* at the Information Center, the cardiotach is available on the telemetry mainframe.
  Note—Arrhythmia analysis must be turned on at the Information Center when using EASI mode.

ECG Lead Sets

The M2601B Transmitter supports two different lead sets (see “Connecting the ECG Cable” on page 3-14). It detects the inserted lead set type and automatically determines the ECG measurement and transmitted leads. The Lead Set Insertion Guide on the device will assist you in ensuring the correct measurement during transmitter usage (see “Connecting the ECG Cable” on page 3-14). The 5-wire lead set can be used for either Standard or EASI electrode configurations. The lead sets are compatible with the 5- and 3-wire lead sets used with the IntelliVue family of monitors.

Important—M2601B Transmitter lead sets are not compatible with M2601A Transmitters.

The electrode placements for the illustrations in this chapter use the AAMI labels and colors. 5-wire lead sets are available with the lead-wire color option. The following table lists the AAMI and IEC electrode locations and colors.

Electrode Locations and Colors

Lead Set Type	Electrode Location	AAMI Electrode Color	IEC Electrode Color
3-wire	LA	Black	Yellow
	RA	White	Red
	LL	Red	Green
5-wire (in Standard Mode)			
	LA	Black	Yellow
	RA	White	Red
	LL	Red	Green
	RL	Green	Black
	V	Brown	White
(in EASI Mode)	S	Black	Yellow
	I	White	Red
	A	Red	Green
	N	Green	Black
	E	Brown	White

ECG Leads Monitored

Depending on the lead set connected to the transmitter, a different set of viewable leads are available at the Information Center. The transmitter can source up to four raw ECG waves. The transmitter automatically recognizes the lead set connected.

If you are using ...	these leads are available
3-wire	If Lead Select is configured off: • Default is II. • To monitor a different lead, change the electrode placement to the lead you want. Then, at the Information Center, select the lead label that reflects the electrode placement. • Choices are I, II, or III. *Note*—The raw ECG is received on Channel 1 as II. If Lead Select is configured on: • Default is II. • If connected to TeleMon, you can select a different lead at TeleMon without moving the electrodes. Choices are I, II, or III. *Note*—The raw ECG is received on Channel 1 as I, II, or III, depending on which lead is selected.

If you are using ...	these leads are available
5-wire (Standard Mode)	I, II, III, aVR, aVL, aVF, MCL, and V Defaults are II, V, III In Standard mode, the raw ECG waves are received as: • Channel 1 = Lead II • Channel 2 = Lead III • Channel 3 = Lead MCL Lead selection is available at the Information Center. *Important*—Do not set the primary and secondary channels to the same lead.
5-wire (EASI Mode)	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 EASI 12-lead selection is available at the Information Center. In EASI mode, the sourced waves are received as: • Channel 1 = Vector 1 (A-I) • Channel 2 = Vector 2 (A-S) • Channel 3 = Vector 3 (E-S) Although you can view and perform ST analysis on all 12 EASI derived leads, arrhythmia monitoring is performed only on the primary and secondary leads selected at the Information Center.

Reconstructed Leads

Reconstruction of 3 and 5 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.

ECG Lead Reconstruction

ECG Lead		Clinical Calculations in terms of electrodes
3-wire	**5-wire Standard**	
I	I	LA-RA
II	**II**	LL-RA
III	**III**	LL-LA
-	MCL	Va-LA, C=Va
-	aVR	RA-(LA+LL)/2
-	aVL	LA-(RA+LL)/2
-	aVF	LL-(LA+RA)/2
-	**V**	C-(RA+LA+LL)/3, C=Va

Setting Up for ECG Monitoring

Task Summary

Step	Action
1	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. • Select sites with intact skin, without impairment of any kind. • Clip or shave hair from site, as necessary • Wash site with soap and water, leaving no soap residue. *Note—Philips does not recommend using ether or pure alcohol, because they dry the skin and increase the resistance.* • Dry thoroughly. • Use ECG skin preparation paper (abrasive) to remove dead skin cells and to improve the conductivity of the electrode site.
2	Check electrodes for moist gel, and attach to the clips/grabbers. If you are not using pre-gelled electrodes, apply electrode gel to the electrodes before placement. *Note*—Gel must be moist to provide a good signal.
3	Place the electrodes on the patient according to the lead placement you have chosen (see "Electrode Placement" on page 3-8). Place the edge down, then "roll down" the rest of the pad. Press firmly around the adhesive edge toward the center. *Note*—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.

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. This helps maintain maximum electrical patient safety.

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

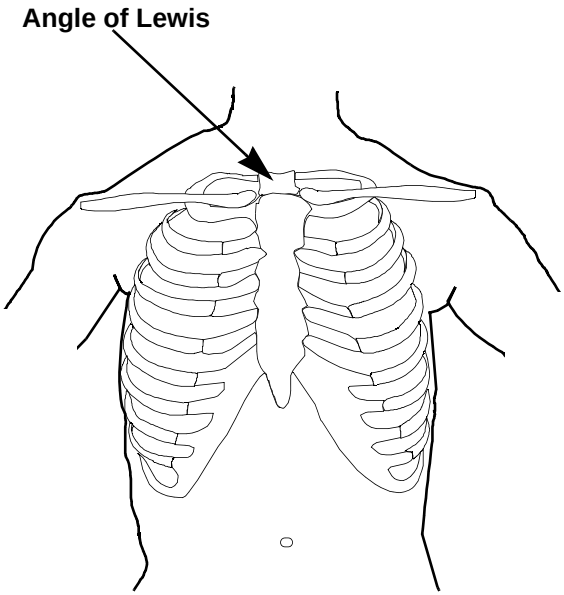
To protect the transmitter from damage during defibrillation, to ensure accurate ECG information, and to provide protection against signal noise and other interference, use only ECG electrodes and cables specified by Philips.

Electrode Placement

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

Philips recommends that electrodes be changed every 24 hours.

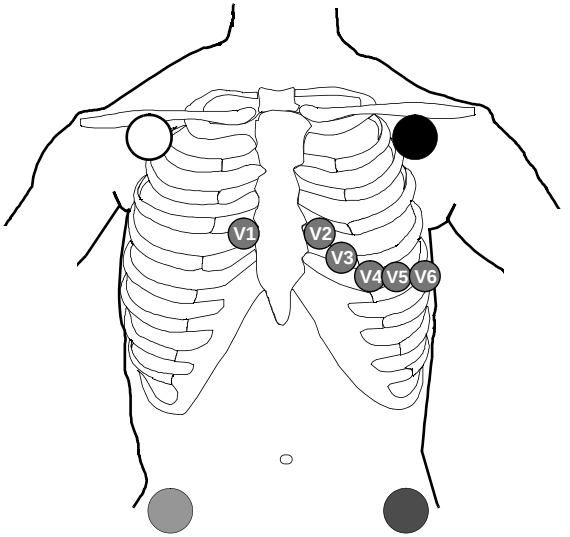
Locating the Fourth Intercostal Space



For accurate chest electrode placement and measurement, it is important to first 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.

5-wire 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
RL	on the right lower abdomen
LL	on the left 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

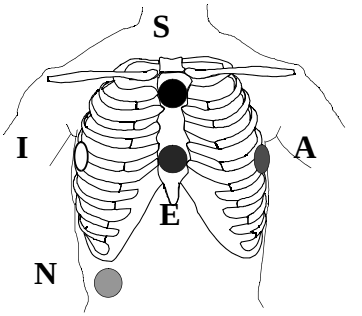
Lead	Placement
V2	on the fourth intercostal space at the left sternal border
V3	midway between the V2 and V4 electrode positions
V4	on the fifth intercostal space at the left midclavicular line
V5	on the left anterior axillary line, horizontal with the V4 electrode position
V6	on the left midaxillary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

5-wire Placement (EASI Mode)

Warning

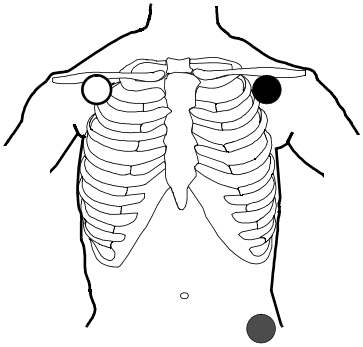
EASI derived 12-lead ECGs and their measurements are approximations to conventional 12-lead ECGs. As the 12-lead ECG derived with EASI is not exactly identical to the 12-lead conventional ECG obtained from an electrocardiograph, it should not be used for diagnostic interpretations.

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
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

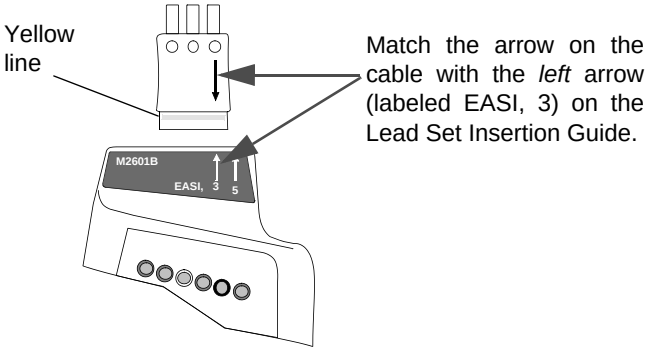
3-wire Placement

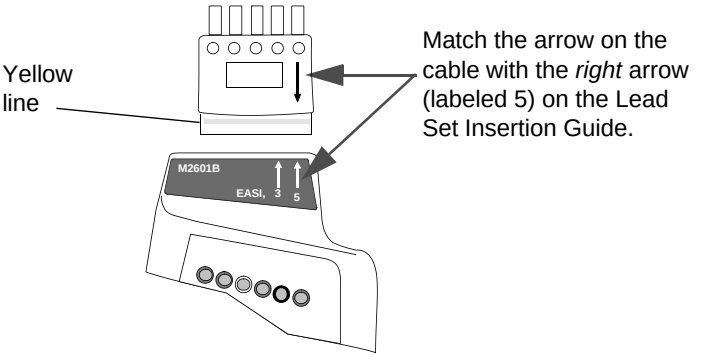
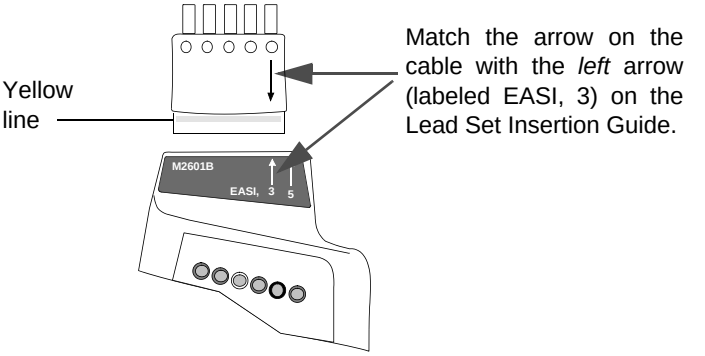


Lead	Placement
RA	directly below the clavicle and near the right shoulder
LA	directly below the clavicle and near the left shoulder
LL	on the left lower abdomen

Connecting the ECG Cable

Task Summary

Step	Action
1	Match the arrow on the ECG cable with the arrow on the Lead Set Insertion Guide according to the lead type you have chosen, and insert the ECG cable into transmitter. *Important*—**Make sure that the cable is pushed *completely* into the transmitter. When correctly inserted, the yellow line at the base of the cable is not visible.**
	3-wire: 

Step	Action
	5-wire *Note*—If you are using the 5-wire lead set 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 lead set and the line is not visible. **Standard Mode:**  **EASI Mode**: 

Step	Action
2	Check that the correct lead indicators are lit for the lead set you are using, and that the EASI indicator light is illuminated appropriately. See “Verifying Electrode Connections” on page 3-17. *Important*—When using 5-wire Standard, note that the EASI indicator **does not** illuminate. When using EASI, the EASI indicator should illuminate for 5 seconds after the lead set is inserted (as well as when the Check button is pressed).

Cable Disconnection

When disconnecting the lead set from the transmitter, grasp the lead block firmly and pull free. Do not pull on the lead wires.

Verifying Electrode Connections

The electrode indicator LEDs (Light Emitting Diodes) 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 lead set status. During routine use of the transmitter for monitoring, all LEDs are off.

Task Summary To verify electrode connections, use the following procedure:

Step	Action
1	Press and hold the **Check** button for 2 seconds
2	**Expected Response**: • If 3-wire cable is attached: Red, White and Black LEDs illuminate, then all turn off. • If 5-wire cable in Standard mode is attached: Red, White, Black, Green & Brown LEDs illuminate, then all turn off. • If using EASI: Red, White, Black, Green & Brown LEDs illuminate, then all turn off. The EASI indicator also illuminates briefly. • If no lead set is attached: all LEDs are off.
3	**Unexpected Response**: Any other response indicates a problem. Check the lead block connection and/or use a new lead set. If the problem is not corrected, contact your Service Provider.

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

Making ECG Adjustments

You can make the following adjustments from the IntelliVue Information Center:

- Change the lead or the lead label.
- Change the wave size.

With 5-wire lead sets, you can monitor two leads. With a 3-wire lead set you can monitor one lead. When monitoring two leads, the first lead is the primary lead. Singlelead arrhythmia analysis uses this lead. It is also the lead used for alarm and delayed recordings. Multilead analysis uses both leads.

If you are not receiving a good ECG wave and the electrodes are securely attached, you should try changing the lead in which you are monitoring.

Bandwidth

Bandwidth is not user adjustable, but is assigned automatically by the Information Center. The settings are:

Setting	Bandwidth
ST off	Monitor (0.5 to 40 Hz)
ST on	ST (0.05 to 40 Hz)

Changing Lead/Label

To change the lead/label place your cursor over the wave in the Patient Window.

- For a 3-wire lead set, apply the electrodes to monitor the lead you want and select the label from the pop-up box to match the placement.

Note—If TeleMon is available, you can change the lead on a 3-wire lead set (if configured for Lead Select). See “ECG Leads Monitored” on page 3-4.

- For a 5-wire lead set, you can change the lead without moving the electrodes.

Adjusting Wave Size

To change the amplitude of the ECG wave on the display or for recordings, place your cursor over the wave in the Patient Window and select the size you want from the pop-up box. There are five sizes available: 1/4 (smallest), 1/2, 1, 2, and 4 (largest).

You can use the 1 mV cal bar on the Patient Window to check the height of the R-wave. If the wave is not at least 0.5 mV high (one-half the size of the cal bar), change the lead.

Monitoring During Leads Off

ECG Fallback and Extended Monitoring occur when the primary and/or secondary leads are in a Leads Off condition for >10 seconds. The system performs this action in an attempt to maintaining monitoring and arrhythmia analysis.

Lead Fallback is used if the primary or secondary lead is available. Extended Monitoring is used if neither is available.

Lead Fallback

Lead Fallback is configured on or off by your Service Provider.

Multilead Analysis

If the system is using multilead analysis, the active secondary lead becomes the primary lead, and the arrhythmia algorithm switches the leads on the display. When the Leads Off condition is corrected, the leads are switched back to their original state. Arrhythmia Relearn does not occur.

Singlelead Analysis

For singlelead analysis, if there are two leads available, the other lead is made the primary lead until the Leads Off condition is corrected. The arrhythmia algorithm performs a Relearn.

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" and is analyzed by the arrhythmia algorithm. Arrhythmia Relearn occurs with transition to/from EASI Lead Fallback.

Extended Monitoring

When both the primary and secondary leads have a Leads Off condition, if another lead is available it becomes the primary lead and the system does a Relearn. This is called Extended Monitoring.

Extended Monitoring applies if:

- Telemetry is configured for Extended Monitoring ON.
- The lead set provides more than two leads (i.e., when using a 5-wire lead set).

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, 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 System 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 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 transmitters or the antenna 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 system's dependability.

Warning

The Philips 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.

Note—The Philips Telemetry System also emits radio frequencies (defined in Chapter 7, “System Safety and Specifications”) that may affect the operation of other devices. Contact the manufacturer of other equipment for possible susceptibility to these frequencies.

The Telemetry Signal

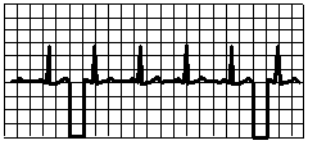
The transmitter worn by the patient acquires the patient's physiological data, amplifies and digitizes it, detects pace pulses and broadcasts this information via radio waves to the antenna system. Since the signal passes through the air, it is susceptible to interference from many sources.

Troubleshooting Signal Disturbance

Dropouts

Because the telemetry system is a wireless system, under certain conditions RF “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 TEL CANNOT ANALYZE, as well as CANNOT ANALYZE ECG or CANNOT ANALYZE ST technical alarms occur.

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 antenna system is custom designed for your unit, so reliable signal reception is only possible where there are receiving antennas. When the signal is too low, the following technical alarms occur:

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

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

- Return the patient to the specified antenna coverage area.
- Put telemetry in Standby mode. See “Standby Mode” on page 1-24.

Warning

If you put telemetry in Standby mode, you *must* remember to turn monitoring back on when the patient returns to the unit.

- If the patient is in the coverage area and is stationary, try moving the location of the transmitter or patient about 6 inches (15 cm.).

Radio Frequency Interference

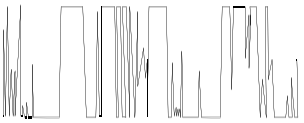
Radio frequency (RF) interference is caused by anything that intrudes into the transmitted electrical signal, such as paging transmitters. We are all familiar with electrical interference in our homes and cars when it causes signal loss or static on a cell phone. These same types of interference can occur with the transmitted telemetry signal. Even though the Philips 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 respiration 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.

Problem	Cause	Remedy
60-Cycle (AC) Interference 	Poor electrode placement. Possible non-grounded instrument near patient.	Re-apply electrodes 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; re-apply the electrodes if necessary, using good skin preparation (see “Setting Up for ECG Monitoring” on page 3-7).
Irregular Baseline 	Poor electrical contact. Respiratory interference. Faulty electrodes. Dry electrodes.	Re-apply electrodes, using good skin preparation (see “Setting Up for ECG Monitoring” on page 3-7). Move electrodes away from areas with greatest movement during respiration.

Problem	Cause	Remedy
Baseline Wander 	Movement of patient. Improperly applied electrodes. Respiratory interference.	Make sure patient is comfortable. Re-apply electrodes, using good skin preparation (see “Setting Up for ECG Monitoring” on page 3-7). Check that patient cable is not pulling electrodes. Move electrodes away from areas with greatest movement during respiration.
Poor Electrode Contact 	Loose electrodes. Defective cables. Lead set not firmly connected.	Change electrodes, using good skin preparation (see “Setting Up for ECG Monitoring” on page 3-7). Replace cables.

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.

Warning

FOR PACED PATIENTS
The output power of the transmitter 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 transmitter 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 Telemetry System. See the *IntelliVue Information Center Instructions for Use* for additional information on monitoring paced patients.

Caution

During defibrillation, monitoring may be temporarily interrupted or distorted. It may take several seconds for the ECG trace to reappear on the screen. After defibrillation, the device will continue to monitor as before; the device settings will not be affected.

ST/AR Arrhythmia Analysis

For information on arrhythmia detection and ST monitoring, refer to the following:

- *IntelliVue Information Center Instructions for Use* and Online Help
- *ST/AR Algorithm - Arrhythmia Monitoring* Application Note (4522 981 93051).
- *ST/AR Algorithm - ST Segment Monitoring* Application Note (4522 981 92851).

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.

ST/AR provides Heart Rate and PVC Rate numerics and alarm detection for the conditions listed in the table below. There are two levels: Basic and Enhanced. Enhanced includes the Basic alarms. See "Physiologic (Patient) Alarms" on page 2-6 for arrhythmia alarm text and descriptions.

Basic & Enhanced Arrhythmia Detection

Basic Arrhythmia Detection	**Enhanced Arrhythmia Detection**	
Asystole	Non-Sustain VT	Multiform PVCs
V Fib/Tach	Vent Rhythm	Irregular HR
V Tach	Run PVCs	
Extreme Brady or Brady yyy < xxx	Pair PVCs	
Extreme Tachy or Tachy yyy > xxx	Pause	
High HR or HR yyy > xxx	Missed Beat	

Basic & Enhanced Arrhythmia Detection

Basic Arrhythmia Detection	Enhanced Arrhythmia Detection	
Low HR or HR yyy < xxx	SVT	
PVCs > xx/min	R-on-T PVCs	
Pacer Not Capturing	Vent Bigeminy	
Pacer Not Pacing	Vent Trigeminy	

Beat classification determined by the ST/AR algorithm is shown on the primary delayed wave in Arrhythmia Analysis at the Information Center. To access the waves with beat annotations, 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 Beat	Blue
S	Supraventricular Premature	Blue
V	Ventricular Premature	Red
?	Questionable	Red
‘	Pacer Mark	Blue

When monitoring is initiated, when the Channel 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.

ECG and ST/AR Alarms

See Chapter 2, “Alarms” for a list of all ECG and arrhythmia alarms.

ST/AR Arrhythmia 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

--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.

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.

4
ST/AR ST Segment Monitoring

This chapter describes the ST/AR ST algorithm for telemetry of the IntelliVue Information Center. It includes the following sections:

ST/AR ST Algorithm

Intended Use

The intended use of the ST/AR ST algorithm for the IntelliVue Information Center is to monitor ST segment elevation or depression for each available telemetry ECG lead and produce 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.

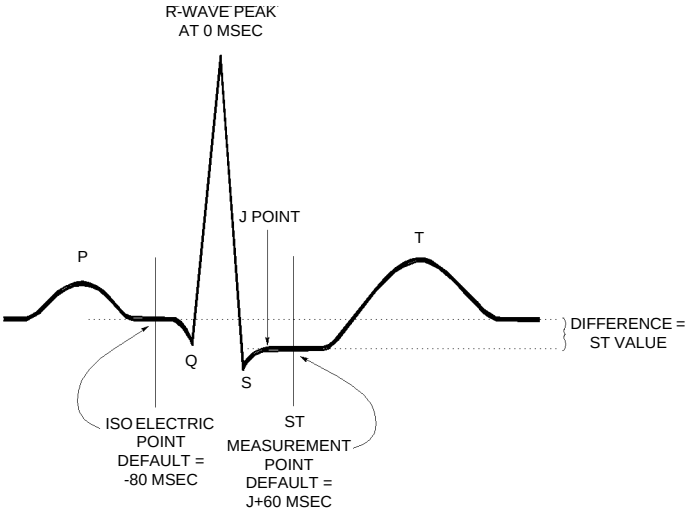
Patient Population

You can perform ST analysis on both non-paced and atrially paced patients. The ST/AR ST algorithm is approved only for adult telemetry-monitored patients. With EASI monitoring, ST analysis is performed on up to 12 leads.

Note—Studies have validated the maximal EASI derived ST measurements on male and female patients with ages from 33 to 82, heights 147 to 185 cm (58 to 73 in), weights 53 to 118 kg (117 to 261 lb) and height-to-weight ratios of 1.41 to 2.99 cm/kg (0.25 to 0.54 in/lb).

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



Warning

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

How the Algorithm Works

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.

ST analysis uses the ST/AR arrhythmia beat classification to select only normal and atrially paced beats for its analysis.

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.

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 depression. You can view ST data in ST Review, Trend Review, and Event Review windows.

EASI ST Analysis

ST/AR ST analysis for EASI derived transmitters is done on all 12 leads. The value presented in the patient sector and Patient Window is “STindx”. 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.

Adjusting Measurement Points

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

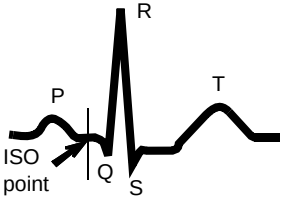
There are three measurement cursors:

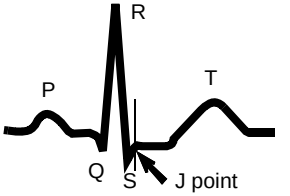
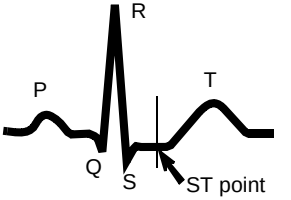
- The ISO measurement cursor positions the isoelectric point in relation to the R-wave peak.
- The J-point cursor positions the J point in relation to the R-wave peak. The purpose of the J point is to correctly position the ST measurement point.
- The ST measurement cursor positions the ST point a fixed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

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

Task Summary

Perform the following steps 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	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. 
4	Adjust the ST point, if necessary, by using the J point as an "anchor" and place the bar at the midpoint of the ST segment. Choices are J + 0, J + 20, J + 40, J + 60, or J + 80). 

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 IntelliVue 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 *IntelliVue Information Center Instructions for Use* or Online Help for directions.

Turning ST On/Off

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

Task Summary To turn ST monitoring on/off perform the following steps:

Step	Action
1	Access the ST Setup Window by clicking the **All Controls** button on the Patient Window then clicking the **ST Setup** button.
2	If you want to turn all ST monitoring on/off click **ST On**.

ST Alarms

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

- 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 *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 Chapter 2, “Alarms” for a list of all ST alarms.

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

ST Alarm Adjustments

Task Summary Make adjustments to ST alarms on the ST Alarms window.

Step	Action
1	Access the ST Alarms window by clicking on the **All Controls** button in the Patient Window then clicking the **ST Alarms** button under Alarm Management and Setup.
2	Make the adjustments on the ST Alarms window. Choices for setting the ST alarm limits are: **Unit Settings—**Click on this button if want to have the specific limits that are pre-set for your unit. **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. *Note*—Smart Limits can be configured to automatically be activated when the patient is connected. See the *IntelliVue Information Center Instructions for Use* for additional information on using smart limits. **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.

5
SpO_2 Monitoring

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

About the Pulse Oximetry Measurement

The M2601B transmitter supports an SpO_2 sensor connection using Fourier Artifact Suppression Technology (FAST). The FAST algorithm provides superior motion artifact rejection and low-perfusion performance. SpO_2 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 is selected at TeleMon, the M2601B Transmitter will provide Continuous SpO_2 measurement (see "SpO_2Measurement when Connected to TeleMon" on page 5-17).

The SpO_2 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 SpO_2 numeric that appears on the monitor will read 97%. The SpO_2 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.
- The amount of light getting 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 SpO_2 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.

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-pitched tone for each pulse detected. The tone (volume, mute) is configured. 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; it should not be used an indication for treatment. The indicator is not functional in Continuous measurement mode.

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

SpO_2 Information for the User

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 SpO_2 alarm signals will be generated at the Information Center. The SpO_2 low limit can be set between 50 and 99% inclusive, in 1% increments. The SpO_2 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 Information Center is 10 seconds.

Pulse rate is also derived from the pulsatile SpO_2 measurement, and displayed results can range from 30 to 300 b/min. There is no alarm function for pulse rate.

The pleth wave (on TeleMon C, if available) 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.

SpO_2 Safety Information

Warning

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.

Avoid placing the SpO_2 sensor on any extremity with an arterial catheter, or intravascular venous infusion line.

Injected dyes such as methylene blue, or intravascular dyshemoglobins such as methemoglobin and carboxyhemoglobin can lead to inaccurate 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 SpO_2 sensor during Continuous SpO_2 monitoring results in a SpO2 NO TRANSDUCER technical alarm. There is no technical alarm for a "No sensor" condition in Spot Check mode.

Preparing for Telemetry SpO_2 Monitoring

The Philips Telemetry System provides remote monitoring of SpO_2 measurement for adult and pediatric patients. You need to prepare your telemetry patient and perform setup tasks for the measurement to display at the IntelliVue Information Center or TeleMon.

Task Summary

Perform the following steps to set up for telemetry SpO_2 monitoring:

Step	Action
1	Select the site and appropriate sensor (see “Selecting an SpO2 Sensor” on page 5-9).
2	Attach the sensor cable to the transmitter (see “Connecting the SpO2 Cable” on page 5-16.
3	Attach the sensor cable to the transmitter (see “Connecting the SpO2 Cable” on page 5-16 • Plug *reusable* transducers directly into the transmitter. • Plug *disposable* transducers into the adapter cable, then plug the adapter cable into the transmitter. Remove the protective backing. Attach the sensor to the appropriate part of the patient's body.
4	If connected to TeleMon, use the pleth wave to check the signal quality.
5	Adjust SpO_2 alarms in the Patient Window.
6	Make other adjustments in the Telemetry Setup Window.

SpO_2 Sensors

Disposable Sensors

Only use disposable sensors 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. Disposable sensors are not available as Philips Medical Systems parts in the USA or Canada. Contact Nellcor® Incorporated.

Reusable Sensors

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 regularly. See the Directions for Use supplied by Nellcor® Incorporated for instructions on preparation and application of disposable sensors.

Warning

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

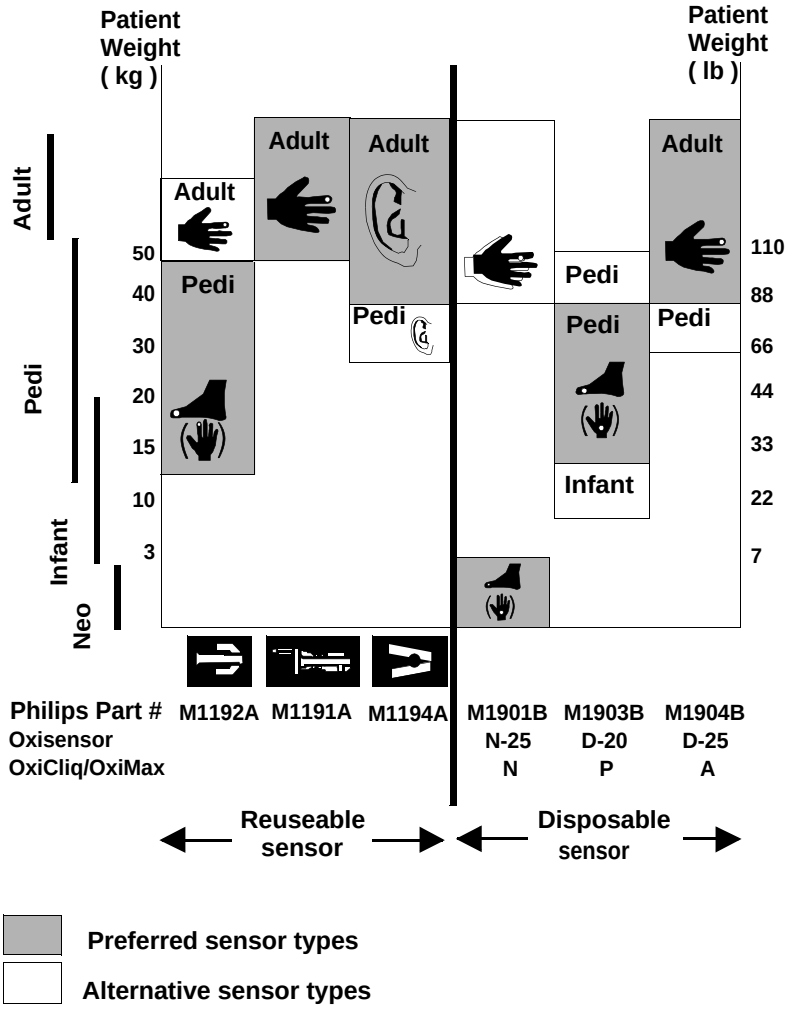
Selecting an SpO_2 Sensor

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

Warning

Use only specified sensors (probes) and cables, otherwise patient injury can result.

“Selecting an SpO2 Sensor” on page 5-10 is a guide in selecting the correct sensor type. To use the figure, find the patient’s weight on the vertical axis. 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.



Selecting an SpO_2 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.

Applying the Sensor

Sensor Application Safety Information

Warning

Failure to apply a sensor properly can reduce the accuracy of the SpO_2 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: Avoid use of excessive pressure at the application site (e.g., sensor applied too tightly, excessive adhesive tape to secure the sensor, clothing or restraints that are too tight). These result in venous pulsations and inaccurate measurement, and may severely obstruct circulation.

Ambient Temperature: Never apply an SpO_2 sensor at ambient temperatures from above 37 ^{o}C (99 ^{o}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

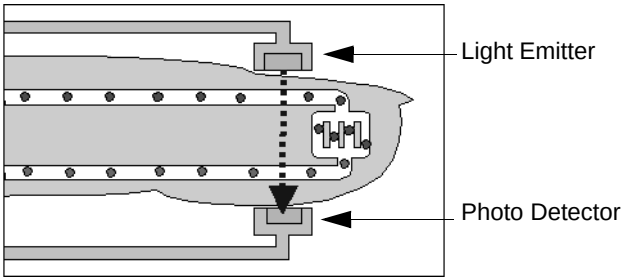
A minimum pulsatile flow must be present at the application site of your patient to obtain measurements.

Avoid sites with impaired perfusion, skin discoloration, excessive motion or nail polish.

Positioning the Sensor

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 photodetector 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.



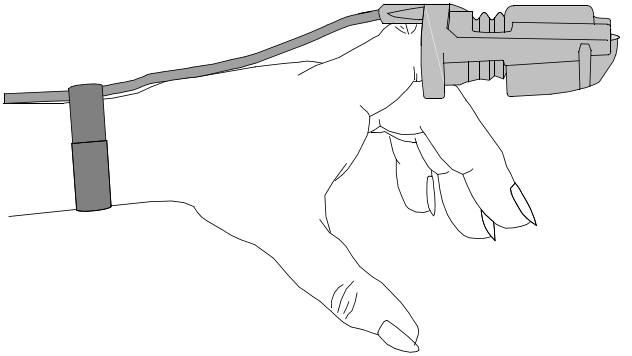
Positioning of the Light Emitter and Photo Detector

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 instructions for use accompanying the sensors; adhering to all warnings and cautions.

Adult Finger Sensor (M1191A)

Place 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.

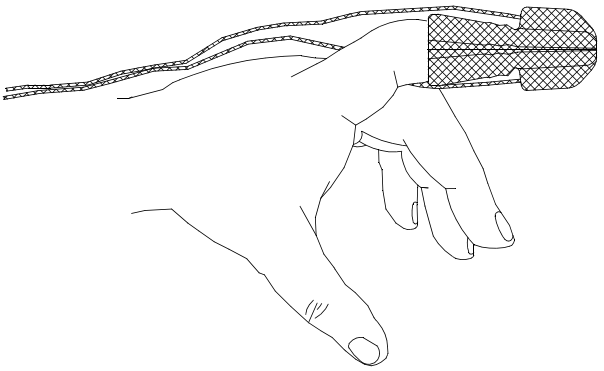


Warning

Failure to apply the sensor properly may cause incorrect measurement of SpO_2. For example, not placing the sensor far enough over the finger can result in inaccurate SpO_2 readings. Placing the sensor too far, so that the finger protrudes from the sensor, can pinch the finger, resulting in inaccurately low SpO_2 readings.

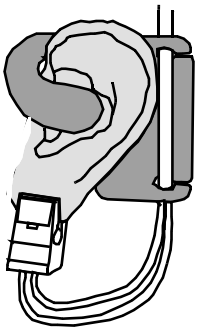
Small Adult/ Pediatric Finger Sensor (M1192A)

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



Ear Clip Sensor (M1194A)

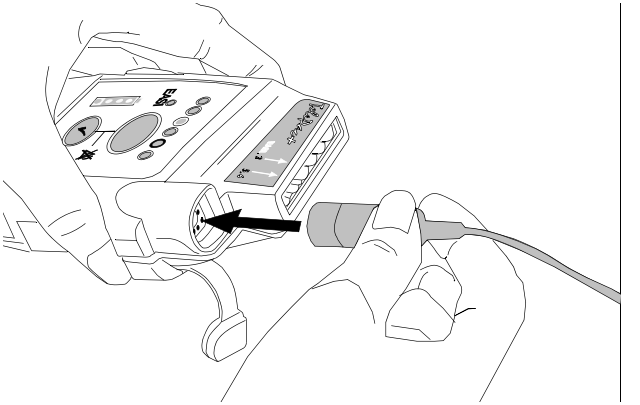
Clip the probe onto the fleshy part of the ear lobe as shown in the diagram below. The plastic fixing mechanism helps to minimize artifact generated by patient motion. Do not position the probe on cartilage or where it presses against the head.



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 SpO_2 Cable

Task Summary

Step	Action
1	Connect the sensor cable to the transmitter. If you are using a disposable sensor, plug the sensor into the adapter cable and plug this cable into the transmitter. Plug reusable sensors directly into the transmitter 

Caution

Extension cables: Do not use extension cables with the transmitter.

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

Making SpO_2 Measurements

SpO_2 measurements can be made continuously, or manually on an as-needed basis (Spot Check). The SpO_2 parameter is turned on/off by inserting/removing the sensor cable into the transmitter. SpO_2 monitoring consumes considerable electrical energy. If the battery power is not at least 25% full, no measurements of SpO_2 can be made.

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

SpO_2Measurement when Connected to TeleMon

When the M2601B transmitter is connected to TeleMon:

- The measurement mode is *always* Continuous.
- You can change the mode. Changes to the mode take effect when the transmitter is disconnected from TeleMon. The following settings will be used:

Mode Setting at TeleMon	Mode at Disconnected Transmitter
Continuous	Continuous
5-minute	Continuous
1-minute	Continuous
Manual	Spot Check

Note—When using the M2601A Transmitter, 5-minute and 1-minute settings are available when disconnected from TeleMon.

Making a Spot Check Measurement

When the transmitter is configured for Spot Check measurement, use the following instructions to take an individual, manual SpO_2 reading from the transmitter.

Task Summary

Step	Action
1	Attach the sensor to the patient.
2	Connect the SpO_2 cable to the transmitter, and check that: • The SpO_2 sensor light turns on. • A low-pitched tone detecting each pulse is audible (unless sounds are muted).
3	After approximately 30 seconds, a tone from the transmitter indicates that a measurement has been completed successfully (single beep), or failed (double beep). If failed, you must retake the measurement. The value, with the measurement time, is displayed at the Information Center, and the sensor light extinguishes. *Note*—The SpO_2 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 transmitter, the Spot Check measurement will be erased from the display, but the SpO_2 measurements will be available in Trend Review.
4	To repeat a Spot Check measurement at the bedside, disconnect then reconnect the SpO_2 cable to the transmitter.

Monitoring SpO_2 Continuously

When the transmitter is configured for Continuous SpO_2 measurement, use the following directions to initiate Continuous SpO_2 monitoring.

Task Summary

Step	Action
1	Insert the SpO_2 cable to the transmitter, and check that the sensor light turns on.
2	Attach the sensor to the patient.
3	After approximately 15 seconds, the value, with the measurement time, is displayed at the Information Center. *Note*—There are no sounds associated with Continuous SpO_2 measurement.
4	To discontinue monitoring, set SpO_2 mode to **off** at the Information Center. If TeleMon is available, connect and change the setting to Spot Check.

Turning SpO_2 Monitoring Off

To turn SpO_2 monitoring off, disconnect the sensor cable from the transmitter. SpO_2 enters a power-down mode after the cable is disconnected from the transmitter, thereby conserving battery life.

SpO_2 should also be turned off at the Information Center. If the transmitter is configured for Continuous SpO_2 measurement and the sensor is removed without turning SpO_2 off, a SpO2 NO TRANSDUCER technical alarm will result.

Important—It is important to disconnect the sensor from the transmitter. Unplugging the sensor from an adapter cable that is connected to the transmitter does NOT provide SpO_2 power-down mode.

Turning the SpO_2 Parameter On/Off

You can turn the SpO_2 parameter on/off at the Information Center by using the Telemetry Setup Window.

Note—If SpO_2 is turned on, the Patient Sector and Patient Window of the Information Center display the numeric with "T" (for example, SpO_2 T 90%) to indicate that the measurement was made via telemetry.

Turning the SpO_2 parameter off at the Information Center also turns off:

- SpO_2 alarms
- SpO_2 display of numerics
- SpO_2 trending

If the transmitter is connected to TeleMon, after you turn SpO_2 *on*, you should adjust the sample rate to match your patient's acuity.

Note—After you turn SpO_2 *off*, setting the sample rate to Spot Check at TeleMon will help you conserve the transmitter's battery life.

Task Summary

Turn the SpO_2 parameter on or off manually by performing the following steps:

Step	Action
1	On the Patient Window click the **All Controls** button.
2	On the All Controls Window click the **Telemetry Setup** button.
3	On the Telemetry Setup Window, under SpO_2, turn the parameter on or off by clicking in the **Parameter ON** checkbox. A check mark in the checkbox indicates that SpO_2 monitoring is on.

SpO_2 Parameter Auto ON

The SpO_2 parameter is automatically turned on at the IntelliVue Information Center if a manual SpO_2 measurement is initiated at the transmitter while in Spot Check mode or the SpO_2 sensor is inserted into the transmitter while the transmitter is in Continuous SpO_2 mode.

When a patient is discharged and the transmitter is in Continuous mode, the SpO_2 parameter is turned off. To reactivate the SpO_2 parameter Auto ON feature from the transmitter, remember to do one of the following when a patient is discharged:

- remove the SpO_2 cable from the transmitter, wait 15 seconds, then reinsert the cable

or

- if using TeleMon, reset the transmitter to Manual (Spot Check) mode.

Note—The SpO_2 parameter Auto ON feature only needs to be reactivated when the transmitter is in Continuous mode at discharge.

Note— SpO_2 can always be turned on and off at the IntelliVue Information Center.

Turning SpO_2 Alarms On/ Off

You can turn SpO_2 alarms on or off by using the Telemetry Setup Window.

Task Summary

Turn SpO_2 alarm on or off by performing the following steps:

Step	Action
1	On the Patient Window click the **All Controls** button.

Step	Action
2	On the All Controls Window click the **Telemetry Setup** button.
3	On the Telemetry Setup Window, under SpO_2, turn alarms on or off by clicking in the **Alarm ON** checkbox. A check mark in the checkbox indicates that SpO_2 alarms are on.

Turning the Pulse Parameter On/Off

If monitoring SpO_2 continuously, the Pulse parameter is available at the IntelliVue Information Center. You can turn the SpO_2 pulse parameter on or off by using the Telemetry Setup Window.

Task Summary

Turn the pulse parameter on or off by performing the following steps:

Step	Action
1	On the Patient Window click the **All Controls** button.
2	On the All Controls Window click the **Telemetry Setup** button.
3	On the Telemetry Setup Window, under Pulse, turn parameter on or off by clicking in the **Parameter ON** checkbox. A check mark in the checkbox indicates that pulse monitoring is on.

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.

Measurement Limitations

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 may 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 may 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 SpO_2 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.

See Appendix B, “Accessory List” for ordering information.

Optimizing Sensor Performance

To get the best results from your SpO_2 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.

SpO_2 Alarms and Technical Alarms

SpO_2 alarms are non-latching. That is, when an SpO_2 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 SpO_2 alarms.

6
Maintenance and Configuration

This chapter describes how to maintain the telemetry equipment and configure the system. It includes the following sections:

Troubleshooting

Basic Troubleshooting

For problems with...	refer to
• ECG measurement	“Optimizing System Performance” on page 3-21 “Technical Alarms (INOPs)” on page 2-11 “Reducing Electromagnetic Interference” on page 7-6
• SpO_2 measurement	“Measurement Limitations” on page 5-25 “Technical Alarms (INOPs)” on page 2-11
• Batteries	“Battery Information” on page 1-29 “Status Check” on page 1-28
• Nurse Call Alarm	Nurse Call may have been turned off for the patient. See “Turning Nurse Call On/Off” on page 1-23.

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 transmitter to an ECG or ECG/SpO_2 simulator. By varying the ECG rate and SpO_2 value, alarms can be generated and confirmed for proper operation.

Maintenance

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.
- Ensure that any needed protective covers are in place.

Important—Do not use the Philips Telemetry Monitoring System for any monitoring procedure on a patient if you identify features which demonstrate impaired functioning of the instrument. Contact the hospital biomedical engineer, or your 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.

Transmitter Cleaning and Ethylene Oxide (EO) Sterilization

The procedures in this section keep the transmitter clean and provide protection against infectious agents and bloodborne pathogens. Both the outside of the transmitter 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 surface contaminants from the device.
- **EO Sterilization**: using EO gas treatment to decontaminate cleaned equipment.

Important—**After exposure, the transmitter must be cleaned or cleaned and EO sterilized as per the instructions contained herein.**

Cleaning the Transmitter

Caution

Use of abrasive cleaning materials, or disinfectants or cleaning agents not listed herein, on any part or component of the M2601B Transmitter may damage the components.

Caution

When cleaning the TeleMon/Service port, do not use any stiff, rigid instruments, tools, or other devices to clean debris in the port, as such actions will damage the connector pins. A forceful water stream may be used after soaking for 5 minutes to flush the port if necessary.

Task Summary

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

Step	Action
1	Remove the batteries and any cables or accessories.
2	Soak the transmitter in 70% isopropyl alcohol or 10% sodium hypochlorite (prepared within 24 hours) for 5 minutes.
3	Wipe the transmitter clean by using a cloth dampened modestly with one of the following approved cleaning agents: • 70% isopropyl alcohol • 10% sodium hypochlorite (prepared within 24 hours)
4	If any visible residue remains in the TeleMon/Service Port, flush the port with a forceful stream of water.
5	Rinse or wipe the transmitter with distilled water.
6	Allow to air-dry, or dry with a non-lint producing cloth.

EO Sterilization

The transmitter can be subjected to EO sterilization four times per year for 2 years.

Equipment must first be cleaned (see “Cleaning the Transmitter” on page 6-4) before this procedure is performed.

Note—If there is concern over cross-contamination due to lead sets or sensors, new lead sets 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 6-10.

Use the following equipment and material to process the transmitter:

1. Ethylene Oxide gas (Allied Signal Oxyfume-2002™ or equivalent).
2. Gas sterilizer manufactured by American Sterilizer Company or other appropriate manufacturer.

EO Sterilization

The following generic procedure can be used to supplement the sterilizer manufacturer's instructions, although the processing times, temperatures, and EO concentrations must be equivalent to those given in this procedure in order to achieve a sterility level of 10E-6.

Task Summary

Step	Action
1	Remove any obvious contamination from the equipment to be processed using approved cleaners.
2	Individually package each transmitter 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^{o}C (130 +/- 5^{o}F).
6	Apply -26 inHg +/- 1 (-12.77 psig +/- .49) vacuum to the sterilizer chamber.
7	Humidify the chamber at 50% +/- 10% relative humidity for 20 to 30 minutes.

Step	Action
8	Taking a minimum of five minutes, slowly introduce EO sterilant until the sterilizer unit pressure gauge reaches 11 +/- 1 psig. *Note*—At this pressure, the concentration of sterilant in the chamber will be 600 +/- 50 mg/liter, regardless of the chamber size.
9	Process the equipment to be processed as follows: Pressure: 11 +/- 1 psig (established in the preceding step). Time: 2-3 hours Temperature: 54.4 +/- 2.8^{o}C (130 +/- 5^{o}F)
10	Extract the gas mixture from the sterilizer as follows: **Warning** **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.)** * See “References” on page 6-10. 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. b. Return the sterilizer chamber to ambient pressure by introducing air that has been bacterially filtered.

Step	Action
11	Air-wash the chamber and material as follows: 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 6-10.

Task Summary

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^{o}C (130 +/- 5^{o}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 transmitter 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 transmitter through the EO sterilization process.

This test allows you to verify that patient information for both ECG and SpO_2 (if you are monitoring pulse oximetry) appear at the Information Center and at the bedside. You can use this procedure with a patient simulator.

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

Task Summary

Test the transmitter 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 transmitter (connectors, battery door opening and closing, Telemetry and Check buttons).
2	At the Information Center, select the telemetry bedside you are testing.

Step	Action
3	Test the transmitter: a. Put fresh batteries in the transmitter and close the battery door. ***Result:*** All six lights should flash, and one light should remain on. b. Attach a lead set to the ECG port, and attach an SpO_2 sensor to the SpO_2 port. If an ECG simulator is available, attach the ECG leads to the simulator and the SpO_2 sensor to yourself. At TeleMon, set the SpO_2 sample rate to Continuous. ***Result:*** An ECG trace and SpO_2 information should be visible on the Information Center display. All transmitter 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	a. Connect the transmitter to TeleMon and observe the ECG waveform and SpO_2 numerics on the TeleMon display. ***Result:*** The ECG waveform and SpO_2 numerics should be displayed on the TeleMon screen.

Receiver Mainframe Cleaning

The receiver mainframe should be kept free of dust and dirt. You can only clean the outside of the receiver mainframe. Wipe the outside of the receiver mainframe clean by wetting a damp cloth or rag with one of the following approved cleaning agents:

- Soap and Water
- Isopropyl Alcohol ($\geq$ 70%)
- Ethyl Alcohol ($\geq$ 70%)
- Hydrogen Peroxide
- Sodium Hypochlorite (chlorine bleach), 5% solution
- Sodium Hypochlorite (chlorine bleach), 10% solution prepared within 24 hours
- Cidex® (consult local laws for use)
- Windex®
- Lysol®

Wipe all cleaned surfaces with distilled water to remove any residue. Allow to air-dry, or dry with a non-lint producing cloth before use.

Configuration

How your telemetry system performs depends in large part on the configuration choices made during system installation. This chapter provides a summary of the factory-set defaults and the alternative configuration choices that relate to clinical practice. Configuration for the telemetry system is performed at the receiver mainframe, except for Philips transmitters, which are configured at the Philips TeleMon C Companion Monitor or using the Service Tool. All receiver settings, except frequency, pertain to all receivers in the mainframe.

Two of the most frequently performed configuration procedures are also included in this chapter.

For complete configuration information, including the impact of individual choices, refer to the *Philips Telemetry System Installation and Configuration Guide* in the *M2600B Documentation Kit* (M2600-90323).

Configuration Settings

M2604A Mainframe

The following table lists the mainframe configuration settings used by the IntelliVue Information Center.

Note—The IntelliVue Information Center does not use the following settings:

- HR Alarm Limits
- Lead Fallback
- Bandwidth
- ST Settings

Item	Factory Default	User Choices
GENERAL ALARM PARAMETERS		
Alarm Suspend	3 Minutes	3 Minutes, Infinite
Alarm Reminder *only applies to:* – SpO_2 – ECG if not arrhythmia monitored	ON	ON, OFF
GENERAL ECG PARAMETERS		
Extended Monitoring	ON	ON, OFF

Item	Factory Default	User Choices
M2601X SERIES TRANSMITTERS ECG PARAMETERS		
Lead Selection - 5 Electrode	Primary = II Secondary = V	Primary = I, II, III, aVR, aVL, aVF, MCL, V Secondary = I, II, III, aVR, aVL, aVF, MCL, V, OFF *Note*—The ECG primary and secondary must be different lead types, and the primary cannot be OFF.
Lead Labelling - 3 Electrode	Primary = II	Primary = I, II, III, MCL
SpO_2 PARAMETERS		
SpO_2 Alarm Limits	High: 100 percent Low: 90 percent	High Range = 51-100 percent Low Range = 50-99 percent (increment of 1)
GENERAL PARAMETERS		
Telemetry Button Function	Nurse Call and Record	Nurse Call, Record, Both, Disabled
Language	English	English, German, French, Dutch, Spanish, Swedish, Italian, Japanese, Norwegian, Danish, Finnish, Portuguese

For configuration of the following items, see the *Philips Telemetry System Installation and Configuration Guide* in the *M2600B Documentation Kit.*

- Auto Self Test
- Self-test Strip
- SDN Unit Number
- SDN Branch Number
- Country Code
- Locale Code
- Frequencies

Philips M2601B Transmitter

The following table lists the configuration settings for the Philips M2601B Transmitter.

Item	Factory Default	User Choices
Lead Selection 3-wire lead set	No	Yes, No
Automatic Shutoff (after 10 minutes)	Yes	No, Yes

For configuration of the following items, see *Philips Telemetry System Installation and Configuration Guide*

- Country Code
- Locale Code
- Frequencies

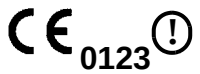
Changing the Configuration

Configuration changes require the Philips TeleMon C Companion Monitor or the Service Tool. If configuration is required (for example to match a replacement Philips transmitter to others in the unit or to change the frequency in case of excessive interference) contact the Service Provider or consult the TeleMon *Service Manual*.

7
System Safety and Specifications

This chapter provides information on regulatory requirements compliance for patient safety, safety-oriented installation and maintenance procedures, and specifications for the Philips Telemetry System. It includes the following sections:

Product Safety



The M2600B Philips Telemetry System, complies with the requirements of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and carries CE-marking accordingly. (CE 0123)

The following symbol ⓘ means that this device is considered Class 2 radio equipment per Directive 1999/5/EC for which Member States may apply restrictions on putting the device into service or placing it on the market. This system is intended to be connected to the publicly available interfaces (PAI) for use throughout EEA.

The Philips Telemetry System also complies with the following international safety requirements for medical electrical equipment:

- IEC 601-1:1998 + 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 Interference
- IEC 60601-1-4:1996 Safety for Programmable Electrical Medical Systems
- IEC 60601-2-49:2001 Multi-parameter Monitor Safety
- EN 865:1997 Particular Requirements for Pulse Oximeters
- AAMI Voluntary Performance Standards for Cardiac Monitors: EC 13: 2002, Clauses 4.2.8 and 5.2.8

The system is protected against the effects of defibrillation.

This system provides continuous operation when in use.

The following accessories and system components are independently CE marked to the Medical Device Directive. They are not covered by the CE marking of the Philips Telemetry System:

- All SpO_2 accessories and equipment
- ECG electrodes
- ECG lead sets

Authorized EU Representative:

Philips Medizinsysteme Boeblingen GmbH
Hewlett-Packard Str. 2
D-71034 Boeblingen
Germany

System Classification

Class I Equipment

M2604A Receiver Mainframe

Class II Equipment

453563647161 Universal Power Converter (UPC)

Characteristic	Definition
Internally Powered Equipment	The M2601B Transmitter is an internally powered device.
Continuous Operation	All equipment is Ordinary Equipment, IPX0, and provides continuous operation.
Type CF Defibrillation Proof	The M2601B Transmitter is Type CF Defibrillation Proof relative to ECG and SpO_2 patient applied parts.
Water Resistance	When placed inside a Philips-specified carrying pouch with the flap closed and snaps secured, the combination of the transmitter and pouch will withstand showering for up to 10 minutes.

Essential Performance

The Philips Telemetry System provides Essential Performance (EP) under normal operating conditions (includes EMC exposure) only as a complete Medical Electrical System, consisting of the M2601B Patient-Connected Device, Philips TeleMon C Companion Monitor (Optional), M2603A/M2604A Receiver/Mainframe, and M3150A IntelliVue Information Center.

The system achieves its Essential Performance exclusively through alarm generation at the Information Center.

The 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 Technical Alarms (INOPs) will be created.

Philips Telemetry System Warnings

The warnings and cautions described below refer to the following devices:

- Philips M2601B Transmitter
- Philips Telemetry System
- IntelliVue Information Center

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

Do not install or use power modules for analog output and antennas within a 2.44 m (8 ft.) radius of the patient. This helps ensure patient electrical safety.

Caution

Installation and setup must be performed by a Philips Medical Systems service representative or designee according to the instructions in *Philips Telemetry Installation & Configuration Guide*, which can be found in the *M2600B Documentation Kit* (order number M2600-90323).

Electromagnetic Compatibility

M2600B Philips Telemetry System Testing

The electromagnetic compatibility (EMC) validation of the Philips M2600B Telemetry System included testing performed according to the international standard for EMC with medical devices. See the Manufacturer's Declaration for details.

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 “Appendix B. Accessory List” in this *Instructions for Use* and in the *Philips Telemetry System Service and Reference Guide*.

Warning

The use of accessories, transducers and cables other than those specified in the Philips Telemetry System 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, you must check that normal operation is possible in the necessary configuration before the product is used.

Reducing Electromagnetic Interference

The system 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 & ST/AR Measurement”.
- 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 product from the source as much as possible. If assistance is needed, contact your local Service Provider.

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.

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 FCC requires the following statement for this device:

The Philips M2600B Telemetry System complies with Part 15 of the Federal Communications Commission (FCC) Rules. Operation is subject to the following two conditions:

- This device may not cause harmful radio frequency interference to a primary licensed user (radio and television stations), and
- 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.

Canadian Radio Equipment Compliance (Canada Only)

For operation in 608-614 MHz

This telemetry device is only permitted for installation in hospitals and health care facilities. This device shall not be operated in mobile vehicles (even ambulances and other vehicles associated with health care facilities). The installer/user of this device shall ensure that it is at least 80 km from the Penticton radio astronomy station (British Columbia latitude: 49° 19’ 12” N, longitude 118° 59’ 56” W). For medical telemetry systems not meeting this 80 km separation (e.g., the Okinagan Valley, British Columbia) the installer/user must coordinate with and obtain the written concurrence of the Director of the Penticton radio astronomy station before the equipment can be installed or operated. The Penticton contact is Tel: 250-493-2277; FAX: 250-493-7767.

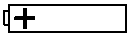
For operation outside 608-614 MHz

Contact your local Industry Canada offices as licensure is required.

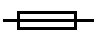
To provide maximum RF shielding and minimum RF interference to the licensed service, this device should be operated indoors and away from windows.

System Symbols

The following is an explanation of the symbols found on the hardware components of the Philips Telemetry System:

Symbol	Explanation
	AC Line Current.
	Active Antenna Combiner.
	Antenna Input.
	Attention. See *Instructions for Use*.
	Bandpass Filter
	Battery Polarity
	Catalog Number

Symbol	Explanation
	Class 2 Equipment
	Data In
	Data In, Data Out
	Data Out
	Date of Manufacture
	DC Voltage
	Do Not Reuse. Use Only Once. Dispose of properly after use in accordance with local regulations.
	Electrical Input

Symbol	Explanation
	Electrical Output.
	Equipotential Grounding System.
	Follow Operating Instructions.
	Frequency Converter
	Fuse Input.
	Grounding system.
	Indoor Use Only
	Line Amplifier
	MAC Address of device. Used for upgrade.

Symbol	Explanation
	Non-ionizing Radiation
	Power On/Off
OPT	Product Option
	Protective Earth (Ground)
	Power Tee
	Receiver Mainframe Malfunction
	Receiver Mainframe. For future use.
SN	Serial Number
	Type CF Defibrillation Proof

Symbol	Explanation
IPX0	The M2600B is rated IPXO in degrees of protection by enclosures; not protected against ingress of water.
US C entela Certified	Complies with applicable Canadian and American medical safety standards.
CE 0123	Compliance to Council Directive 93/42/EEC (Medical Device Directive)
!	Class 2 Radio equipment identifier (1999/5/EC): Member states may apply restrictions on putting this device into service or placing on the market. This device is intended to be connected to the publicly available interfaces (PAI) for use throughout the EEA
Rx	Federal Law restricts this device in the United States to sale by or on the order of a physician.

Type CF Defibrillation Proof

The following symbol identifies a device that is Type CF Defibrillation Proof.

TYPE CF
DEFIBRILLATION PROOF

Type CF Defibrillation Proof equipment is protected against defibrillation (DEFIBRILLATION-PROOF) and is a TYPE CF APPLIED PART.

Installation and Maintenance Safety

Caution

Installation and setup must be performed by a Philips Medical Systems service representative or designee, except for transmitters purchased individually. These can be installed by hospital personnel according to instructions in the *Installation and Configuration Guide* included in the *M2600B Documentation Kit*.

Installation

Environment

Follow the instructions below to ensure a completely safe electrical installation. The environment where the Philips Telemetry System will be used should be relatively free from vibration, dust, corrosive or explosive gases, extremes of temperature, humidity, and so on. For a cabinet mounted installation, allow sufficient room at the front for operation and sufficient room at the rear for servicing with the cabinet access door open.

The Philips Telemetry System operates within specifications at ambient temperatures between 0ºC (32^{o}F) and 55ºC (131^{o}F). The transmitter ambient temperature specification is between 0ºC (32^{o}F) and 37^{o}C (99^{o}F). Ambient temperatures which exceed these limits could effect the accuracy of the

instrument and cause damage to the components and circuits. Allow at least 5 cm (2 inches) clearance around the instrument for proper air circulation.

Grounding

To protect hospital personnel, the cabinet of the Philips Telemetry System must be grounded. Accordingly, the system is equipped with a detachable 3-wire cable which grounds the instrument to the power line ground (protective earth) when plugged into an appropriate 3-wire receptacle. If a 3-wire receptacle is not available, consult the hospital electrician.

Warning

Do not use a 3-wire to 2-wire adapter with this instrument. This ensures optimal electrical safety.

Condensation

Make sure that during operation, the instrument is free of condensation. Condensation can form when equipment is moved from one building to another, thus being exposed to moisture and difference in temperature.

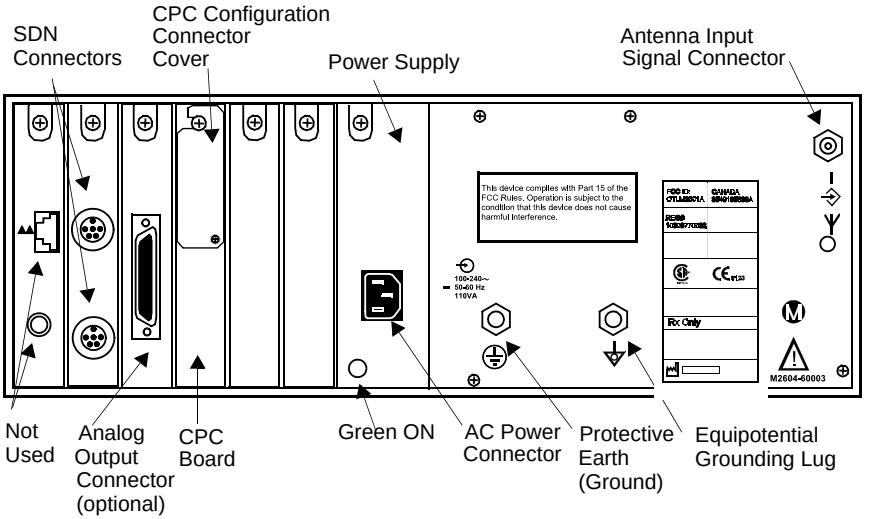
Warning

Possible explosive hazard if used in the presence of flammable anesthetics.

Receiver Mainframe

Rear Panel

The rear panel of the receiver mainframe is shown below.



The back of the mainframe should be removed only by qualified service personnel. To remove the protective cover, unfasten screws, remove tab(s) from slot(s), and lift the cover section off.

Connectors

The connectors on the rear panel of the receiver mainframe are:

Connector	Description
AC Power	3-pin connector, used to input the local line voltage. Mainframe plug is a standard IEC mains inlet receptacle.
Analog Output (Patient Monitor/Holter Interface) - optional	High-density 50-pin SCSI connector to send analog signal to output connector box
Antenna Input Signal	BNC coaxial connector. Max voltage +25V DC

Connector	Description
Equipotential Grounding Lug	Grounding stud connector, used to equalize the grounding potential between products (see “Secondary Ground Wire”, below)
SDN	Upstream and downstream connectors that connect to the Philips monitoring network

Secondary Ground Wire

A secondary ground wire is provided with this instrument to comply with IEC-60601-1-1. This wire ensures against excessive chassis leakage current in the event of a single fault in the health care facility's primary grounding means.

It is recommended that the secondary ground wire be used to connect the Equipotential Grounding Lug to a ground source separate from the primary grounding source found in the instrument's power source.

Note—After servicing, be certain to reconnect the secondary ground wire.

Warning

Removal of the secondary grounding wire from the rear of the product voids the IEC approval.

Lifting the Receiver Mainframe

The weight of the receiver mainframe is 13.8 kg (30.5 lb.). When carrying the mainframe, please use proper lifting techniques

Antenna Amplifiers

The antenna amplifiers must be operated only with the Power Supply (AC/DC Adapter), and must be operated at a minimal distance of 2.43 meters (8 feet) from the patient.

M26XXA/M14XX Series Antenna Components

For all voltages, use part number 453563647161.

Patient Monitor/Holter Interface Option

If using the optional Patient Monitor/Holter Interface (Analog Output), the connector box must only be operated with the appropriate power supply) and must be operated at a minimum distance of 2.43 meters (8 feet) from the patient.

For all voltages, use Universal Power Converter (UPC), part number 453563647161.

Preventive Maintenance

Preventive maintenance should be performed by a qualified service person. The Safety and Performance Tests, and what to do if the equipment does not meet these specifications, are described in the *Philips Telemetry System Service and Reference Guide* in the *M2600B Documentation Kit*. Contact your biomedical department if your equipment needs testing for safety or performance.

End of Life

There is no specific, predetermined end of life to the Philips Telemetry System or any of its component products. Philips Medical Systems provides service, support and replacement parts and assemblies throughout the support life of the products that allow them to be repaired should any component of the system fail. Please refer to the *Philips Telemetry System Service and Reference Guide* for instructions on how to obtain service or replacement parts and for instructions on preventative maintenance. Your local Philips Medical Systems sales or service representative can provide you information regarding the support life of your products.

Additional Safety Information

Warning

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

Warning

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

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

Strangulation Hazard! Under no circumstances should any pouch be tied solely around a patient's neck.

Warning

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

Software Hazard Prevention

Potential hazards arising from errors in the software program have been identified. Mitigations applied to reduce the associated risk of such hazards are included as part of the Risk Management Clinical Evaluation, and Verification and Validation phases of the product's development.

System Specifications

This section lists the specifications for battery life, environmental and electrical power specifications for the hardware components of the system, and measurement specifications.

For complete specifications, see the *M2600B Documentation Kit.*

Battery Life Specifications

Equipment	Specification
Battery Type	2 fresh disposable AA alkaline batteries

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

Operating Mode	Battery Life	Battery Life Japanese Version
ECG Only	42.2 hours, typically	47.8 hours, typically
ECG/SpO_2 Continuous	17.3 hours, typically	18.2 hours, typically
ECG/SpO_2 Spot Check	between 17 hours and 42 hours, depending on usage rate	between 18 hours and 47 hours, depending on usage rate

Environmental Specifications

For all hardware components of the Philips Telemetry System except Philips transmitters and reusable pulse oximetry sensors

Operating

Temperature Range: 0 to 55ºC (32 to 131ºF)

Altitude Range: Up to 4570 m (15,000 ft.)

Humidity Range: 15 to 95% relative humidity

Storage

Temperature Range: -40 to +70ºC (-40 to +158ºF)

Altitude Range: Up to 4570 m (15, 000 ft.)

Humidity Range: 90% relative humidity maximum

For Philips Transmitters

Operating Temperature: 0 to 37 ^{o}C (32 to 99 ^{o}F)
Operating Humidity: $\leq$ 95% RH at 40 ^{o}C (104 ^{o}F) non-condensing
Storage Temperature: -40 ^{o}C to 60 ^{o}C (-40 to 120 ^{o}F) without batteries
Storage Humidity: $\leq$ 90% RH at 60 ^{o}C (120 ^{o}F) without batteries
Altitude, Operating and Non-operating: 0 to 3048 m (10,000 ft.)

For Philips Reusable Pulse Oximetry Sensors

Operating

Temperature Range: 15-37ºC (50-98.6º F)

Altitude Range: Up to 4570 m (15,000 ft.)

Humidity Range: 95% relative humidity at 37º C (98.6º F) maximum

Storage

Temperature Range: -40 to 70º C (-40 to 158º F)

Altitude Range: Up to 4570 m (15,000 ft.)

Storage Humidity: 95% relative humidity at 65º C (150º F) maximum

Water Resistance

The transmitter can be used to monitor a patient in the shower for up to 10 minutes only when placed inside a Philips carrying pouch with the flap closed and snaps secured. The transmitter will not be damaged if it is accidentally immersed in liquid for up to 5 minutes.

After showering, perform the following steps to continue monitoring:

1. Pat dry the lead set connections at the electrodes.
2. Wipe the lead wires with care.
3. If wet, dry the outside of the transmitter 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 transmitter should not be used for monitoring if the battery compartment is wet. Remove the batteries and wipe the compartment dry before continued monitoring use.

Warning

If the transmitter is used while showering a patient or is accidentally immersed in liquid, detection of "leads off" conditions may be compromised. Appropriate clinical precautions should be taken.

Electrical Power Specifications

Note—Specifications for earlier releases of the product may vary slightly.

M2601B Transmitters

Frequency Range
406-480 MHz, 590-614 MHz,
608-614 WMTS band, depending on option

Synthesizer Step Size
12.5 KHz

RF Output Power @ 25^{o}C
Non-Japan transmitter: option #001 to option # 008: 6.5 dBm, +1.6/-2.0 dB (2.8 mW to 6.5 mW) not to exceed 10 dBm into Antenna load

Japan only: +0.8/-3.0 dB (0.5 mW to 1.2 mW) into Antenna load

Adjacent Channel Power
< - 63 dBm at 25 KHz offset

Frequency Accuracy
Frequency @25^{o}C +/- 2.5 ppm @ (0 - 45^{o}C)

Occupied Bandwidth per FCC
≤ 13 KHz

Defibrillator Protection
Transmitter ECG input protected against 400 joules discharge into 50 Ohm load

Batteries
Two disposable 1.5V Alkaline batteries

M2604A Receiver Main Frame with 453563489161 Power Supply

Input Voltage
100-240 VAC

Frequency Range
50 to 60 Hz

Power Consumption
For M2604A: 110 VA maximum, average with 8 M2603A receiver modules

Controls
Front Panel: none
Rear Panel: none

Indicators
Front Panel: Green Instrument Power On LED
Red Instrument Malfunction LED
Rear Panel: Green Power Supply On LED

Connections (rear)
AC Power connector
Analog Output connector
Antenna Input Signal connector
Grounding lug
Downstream SDN connector
Upstream SDN connector
CPC Configuration connector

Radiated Immunity
3 Volts/Meter outside of operating receiver bands

M2603A Receiver Module

Frequency Tuning
Programmable, synthesizer, PLL controlled.

Channel Spacing
25 kHz.

Carrier Frequency Range
Frequency range depends on transmitter option

Patient Monitor Holter Recorder Interface (Analog Output) Option J01

Power Module
453563647161

Input Voltage
100-240 VAC +/- 10%

Frequency Range
47 - 63 Hz.

Power Consumption
33 VA maximum

Analog Output Gain (from output of receiver module)
High-level outputs: 500 ± 5%
Low-level outputs: 1 +7%/-6%

Inoperative Mode (Technical Alarm Condition) Output Level
High-level output: 10.8 volts ± 1.2 volts
Low-level output: >100 megohms with respect to reference electrode

Delay from Transmitter Input to Analog Output
400 milliseconds max -- Philips transmitter
Not intended for use with synchronized cardioversion due to processing delay.

Indicators
Output Connector Box; Status and Power LEDs

Connections
Output Connector Box: Input (50-pin jack); Input (Power Module); Output (8 pairs of 9-pin D connectors)
Analog Output Card: Output (50-pin jack)

Bedside Attenuator: Output (3-conductor phone jack)
Holter Attenuator: Output (set of 5-button connectors)

ECG Bandwidth
M2601B: 0.5 - 40 Hz

To ensure proper operation, installation and setup must be performed by a Philips Medical Systems service representative or designee according to the instructions in *Patient Monitor/ Holter Recorder Interface (Analog Output) Installation Note* (part number M2600-90194).

Antenna System Specifications

M2606A Line Amplifier

Input Voltage
19-32 VDC

Current Requirements
38 mA, maximum

Power Consumption
0.75 Watts, average

RF Frequency Range
406-650 MHz

RF Gain
12.0 dB typical at 406 MHz
12.7 dB typical at 465 MHz
13.3 dB typical at 611 MHz
13.2 dB typical at 650 MHz

Indicators
Green LED indicates DC power is applied to the RF Output connector.
Yellow LED indicates DC power is applied to the RF Input connector.

M2607A Multiple Unit Power Supply

Note—M2607A specifications cover both power module and power tee.

Input Voltage
CE Mark Power Module 453563647161: 100-240 VAC +/- 10%

Frequency Range
47-63 Hz

RF Frequency Range
406-650 MHz

Power Consumption
33 VA maximum

Output Voltage
23 VDC nominal

Output Current
1 Amp maximum (Limited by the circuit breaker in the power tee)

Indicators
Green LED is on when power is present.

M2608A Active Antenna/ Combiner

Input Voltage
19 - 32 VDC

Input Current
62 mA maximum

Power Consumption
1.1 Watts average (2.0 Watts maximum)

RF Frequency Range
406-650 MHz

RF Gain

Antenna Port	9.7 dB +/- 1.0 dB at 406 MHz
	10.2 dB +/- 1.0 dB at 465 MHz
	9.7 dB +/- 1.0 dB at 611 MHz
	9.7 dB +/- 1.5 dB at 650 MHz
Line Port	3.2 dB +/- 0.7 dB at 406 MHz
	3.5 dB +/- 0.3 dB at 465 MHz
	3.9 dB +/- 0.7 dB at 611 MHz
	4.0 dB +/- 0.7 dB at 650 MHz

Indicators
Green LED indicates DC power/signal cable connected correctly.

Red LED indicates DC power/signal cable connected incorrectly.

M2609A Attenuator

Current Carrying Capacity

Maximum DC Voltage: +30 VDC maximum

Maximum DC Current: 1 A maximum

RF Frequency Range:

406-650 MHz

RF Attenuation

1-9 dB in increments of 1 dB, based on option

M2612A Bandpass Filter

Current Carrying Capacity

Maximum DC Voltage: 32 Volts

Maximum DC Current: 1 A

Power Requirements

Negligible

RF Frequency Range

#004	430-440 MHz
#005	440-450 MHz
#006	450-460 MHz
#007	460-470 MHz
#034	590-596 MHz
#035	596-602 MHz
#036	602-608 MHz
#037	608-614 MHz

Indicators

Green LED is ON when power is present.

M2616A External Frequency Converter

Input Voltage
CE Mark Power Module 453563647161: 100-240 VAC +/- 10%

Frequency Range
47-63 Hz

Power Consumption
14.0 VA maximum

RF Input Frequency Range
590-632 MHz

RF Output Frequency Ranges

#130	460-502 MHz
#136	454-496 MHz
#142	448-490 MHz
#148	442-484 MHz
#154	436-478 MHz
#160	430-472 MHz
#166	424-466 MHz

Indicators
Green LED is ON when power is present.

Measurement Specifications

ECG

ECG channel transmitted leads

3 electrodes

Channel #1: I, II, or III

5 electrodes

Channel #1: II
Channel #2: III
Channel #3: MCL

5 electrodes, EASI

Channel #1: Vai
Channel #2: Vas
Channel #3: Ves

Resolution

5 µV

ECG Input

Differential, defibrillator protected against 400 joules discharge into a 50 ohm load

Input Impedance

> 5 megohms (@ 10 Hz

Input Dynamic Range

+/- 9 mmV (EASI mode, +/-4.7mV)

DC Offset Range

+/- 320 mV

CMRR

+/- 90 dB @ 50, 60 Hz

Bandwidth +/- 3 dB

0.05 to 40 Hz

Gain Accuracy

+/- 5% at 25^{o}C (77^{o}F)

Noise Referred to ECG Input

AAMI: 30 µV

Lead Wires

3 or 5-wire set. 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)

Positive pacers

Amplitude	Width
+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

Negative pacers

Amplitude	Width
-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

EMC Performance limits, radiated immunity

Meets Essential Performance, No HR, PVC or Alarm error. But may observe some waveform disturbance in the range 45.00 to 65.00 MHz at levels greater than 2.0 Vrms.

Cardiotach Alarm (Standard ECG only)

Information Center selectable, in 5 b/min. increments.

High: 20 - 250 b/min.

Low: 15 - 245 b/min.

Cardiotach Display (Standard ECG only): 15 - 300 b/min.

Accuracy

Gain: +/- 5% at 25^{o} C (77^{o} F)

Cardiotach (Standard ECG only): +/- 3 beats plus +/- 2% of heart rate for constant rate input.

At fewer than 15 b/min., the heart rate indication is 0.

Cardiotach Alarm (Standard ECG only): +/- 1 b/min., of displayed value

Display

Displayed values are presented in whole numbers.

SpO_2

Measurement Range (Calibration and Display)
0-100%

Display of SpO_2 Numerics
SpO_2 values are displayed as xxx % SpO_2 to meet ISO/EN standard EN 865

Accuracy
See tables, following

Resolution
1%

SpO_2 Numerics Averaging
10 seconds

Note—The update rate for the SpO2 pulse oximetry value and pulse rate is typically 1 second. This can be extended to a max. 60 s when NIBP is measured on the same limb, with a corresponding INOP message after a max. of 30 s, indicating that the displayed values are not current values. The effect of SpO2 pulse oximetry on data averaging and other signal processing on the displayed and transmitted data values of SpO2 and pulse rate is controllable by the host system in the range from 5 s to 20 s with a default averaging of 10 s.

SpO_2 & Pulse Numerics - Update Rate
Transmitted once per second

Pleth Wave - Sampling Rate
125 sps

Technical Alarms
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 - 300 b/min.

Accuracy: +/- 2%

Resolution: 1 b/min.

Wavelength Range
500 to 1000 nm

Note—Information about wavelength range can be especially useful to clinicians (e.g., clinicians performing photodynamic therapy).

Maximum Optical Output Power
<=15 mW

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

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

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

Optional Patient Monitor/ Holter Interface (Analog Output)

This chapter describes the optional Patient Monitor/Holter Interface (Analog Output). It includes the following sections:

Overview

The optional Patient Monitor/Holter Interface (Analog Output) gives the Philips Telemetry System the capability of providing ECG outputs to bedside monitors, holter monitors, and other recording devices. This option is not available for telemetry systems with EASI monitoring.

Warning

The Patient Monitor/Holter Interface (Analog Output) Option is intended for display and recording purposes only. The following should not be used with this option:

- **Synchronized cardioversion**
- **Intra-aortic balloon pump**

Inherent delays in the telemetry transmitter, receiver, and the analog output processing cause significant time lags between actual ECG occurrence and the signal required to trigger the defibrillator or intra-aortic balloon pump. Failure to adhere to this warning could cause serious injury to the patient.

Correct Labeling

To ensure correct lead labeling at the bedside monitor, the following should be used:

- Correct bedside monitor cable. See the table on page A-4.
- Standard lead placement
- Valid lead selection at the bedside monitor. See “Lead Placement and Selection” on page A-5.

Not adhering to these recommendations may result in mislabeled leads or an invalid display.

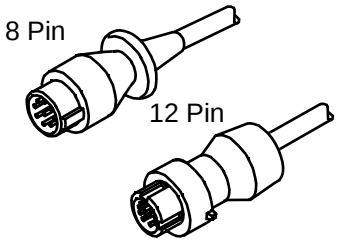
Analog Output Bedside Monitor Cables

To connect the telemetry transmitter to the bedside monitor via the optional Patient Monitor/Holter Interface (Analog Output), you will need an analog output bedside monitor cable.

The end of the cable that connects to the bedside monitor will have either a small 12-pin connector or a larger 8-pin connector (See the illustration below).

The other end of the cable has a phone plug connector, and it plugs into the wallplate.

Note—When using the analog output option for the Philips Telemetry System, this cable will replace the bedside monitor patient cable.



There are four different analog output bedside monitor cables. The cable you use depends upon whether the input connector on your bedside monitor is 8-pin or 12-pin and whether your transmitter lead set is 3- or 5-wire.

The table on page A-5 summarizes the proper cable selection. The 3-wire cables can be distinguished from the 5-wire cable by the attached label (see page A-5).

The lead set type also determines which are the valid leads to be selected at the bedside. Appropriate use of each cable type is illustrated on a label attached to the cable (see page A-5).

The following table shows all available analog output bedside monitoring cables.

Lead Set	Bedside Monitor Cable Connector	Analog Output Bedside Monitor Cable
3-wire lead set	8-pin (large)	HP78599AI-#K71
	12-pin (small)	HP78599AI-#K72
5-wire lead set	8-pin (large)	HP78599AI-#K73
	12-pin (small)	HP78599AI-#K74

Caution

To ensure correct lead labeling at the bedside monitor, it is important that you use the correct bedside monitor cable.

Lead Placement and Selection

To ensure valid waves with the correct lead label, you must remember to use the following:

- Standard lead placement (shown on the telemetry transmitter case and in further detail in IntelliVue Information Center or TeleMon On-line Help).
- Valid lead selection (performed at the bedside monitor)

The following table summarizes recommended lead placement and selection.

Lead Set	Lead Placement	Valid Lead Selection on Bedside Monitor
3-wire	Standard	II
5-wire	Standard	II, MCL

Caution

To ensure correct lead labeling at the bedside monitor, standard lead placement and valid lead selection must be used. Not adhering to these recommendations may result in mislabeled leads or an invalid display.

Using Non-Standard Lead Placement

With the 3- and 5-wire lead set, you can use non-standard lead placement, but you must still use a valid lead label selection at the bedside monitor.

This will give you the desired waveform, but it will result in a mislabeled lead at the bedside monitor.

Controls for Telemetry Setup

The interaction with ECG depends on how the system is installed. If it is installed so that you can make changes from the IntelliVue Information Center, the interface for lead and size selection is the same as described in “Changing Lead/Label” on page 3-18. If not, make adjustments at the bedside monitor.

Functionality with Paced Waves

In order for paced waves to be processed correctly by bedside monitors using the analog outputs, the pace pulses must be artificially reconstructed and inserted into the analog output signals. The synthesized pace pulse is very narrow and may not be visible at the bedside display, depending on the type of monitor used.

Warning

To ensure proper cardiotach performance, diagnostic bandwidth (filter off) should be selected at the bedside monitor when monitoring paced patients with a transmitter.

Technical Alarms (Inoperative Conditions)

With the Patient Monitor/Holter Interface (Analog Output) Option, the following telemetry technical alarms (inoperative conditions) will appear as a LEADS OFF message at the bedside monitor.

1. LEADS OFF
2. NO SIGNAL
3. TEL CANNOT ANALYZE
4. REPLACE BATTERY
5. INTERFERENCE
6. RECEIVER MALF
7. NO RECEIVER
8. TRANSMITTER MALF
9. ECG EQUIP MALF
10. TRANSMITTER OFF
11. INVALID LEAD SET

If telemetry controls are located at the bedside monitor, (see “Controls for Telemetry Setup” on page A-6, these technical alarms appear as a LEADS OFF message at the IntelliVue Information Center.

Note—See Chapter 2, “Alarms” for information about the specific alarm messages.

Holter Interface

If you are using a holter monitor, it should be connected to a holter wallplate.

Warning

Using a holter wallplate to interface to a bedside monitor could result in mislabeled leads.

B
Accessory List

This appendix lists all ECG and SpO_2 accessories that can be used with the transmitter.

For additional information on connecting and using these 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**.

Accessory Safety

Warning

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

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

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

Transmitter Accessories

Pouches

Order Number	Description
989803137831	Telemetry pouch, box of 50
989803140371	Telemetry pouch, case of 200

Protective Covers

Order Number	Description
989803140431	Protective Cover for TeleMon/Service Port, ECG-only device
989803140441	Protective Cover for SpO_2 Port
989803140451	Protective Cover for TeleMon/Service Port, ECG/SpO_2 device

ECG Accessories

Electrodes

Order Number	Description
M2202A	60 packages of 5 radio translucent foam electrodes (300 per box)
40489E	10 packages of 30 paper tape electrodes (300 per box)

Order Number	Description
40493D	60 packages of 5 foam electrodes (300 per box)
40493E	10 packages of 30 foam electrodes (300 per box)

Lead Sets

Order Number	Description
989803133831	3-wire, patient cable set, 79 cm (30”), AAMI, Snap
989803133841	3-wire, patient cable set, 79 cm (30”), AAMI, Grabber
989803133851	3-wire, patient cable set, 79 cm (30”), IEC, Snap
989803133861	3-wire, patient cable set, 79 cm (30”), IEC, Grabber
989803133871	5-wire, patient cable set, 79 cm (30”), AAMI, Snap
989803133881	5-wire, patient cable set, 79 cm (30”), AAMI, Grabber
989803133891	5-wire, patient cable set, 79 cm (30”), IEC, Snap
989803133901	5-wire, patient cable set, 79 cm (30”), IEC, Grabber
989803137241	Colored 5-wire, patient cable set, 79 cm (30”), AAMI, Snap
989803137251	Colored 5-wire, patient cable set, 79 cm (30”), AAMI, Grabber
989803137261	Colored 5-wire, patient cable set, 79 cm (30”), IEC, Snap
989803137271	Colored 5-wire, patient cable set, 79 cm (30”), IEC, Grabber

Skin Prep Paper

Order Number	Description
989803134771	Skin preparation sheets, 10 preps/sheet, 10 sheets/ package

Alignment Guides

Order Number	Description
989803140401	Single, package of 10
989803140411	Single connected, package of 10
989803140421	Double, package of 10

Trunk Cable

Order Number	Description
M1949A	10-wire ECG trunk cable

SpO_2 Accessories

Reusable Sensors

Order Number	Description
M1191A	Philips Adult finger, 2 m (6.6 feet)
M1191AL	Philips Adult finger, 3 m (9.8 feet)
M1191NL	Philips Adult finger, 3 m (9.8 feet)

Order Number	Description
M1192A	Philips Pediatric finger 1.5 m (4.9 feet)
M1192N	Philips Pediatric finger, 1.5 m (4.9 feet)
M1194A	Philips Adult & Pediatric ear, 1.5 m (4.9 feet)
M1194N	Philips Adult & Pediatric ear, 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. 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)
* Uses reusable OC-3 Sensor Cable.	

Adapter Cables

Note—Adapter cables are not available from Philips in Canada or Japan. In those countries, contact Nellcor Incorporated directly

Order Number	Description
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)

Wristband

Order Number	Description
M1627A	10 bands per pack

C
Sales and Support Offices

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

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