12-Lead ECG

For Monitoring and Diagnostic Use
Application Note

This paper:

The goal of this application note is to provide the clinician with the proper use of the 12-lead ECGs modalities.

- Describe the system capability and its components.
- Explain how to acquire a 12-lead ECG.
- Reviews the conventional 12-lead electrode placement and describes how to check that the electrodes are correctly placed.
- Reviews the modified electrode placement (Mason-Likar) and summarizes its benefits and limitations.
- Discusses signal quality and filter use.
- Explains common problems seen in waveforms for both conventional and modified electrode placement.
- Explains the Philips 12-Lead ECG Analysis Algorithm
- Explains the format of 12-lead ECG reports.

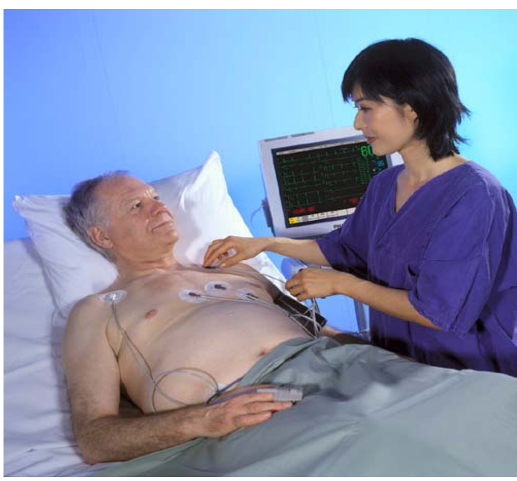
Introduction

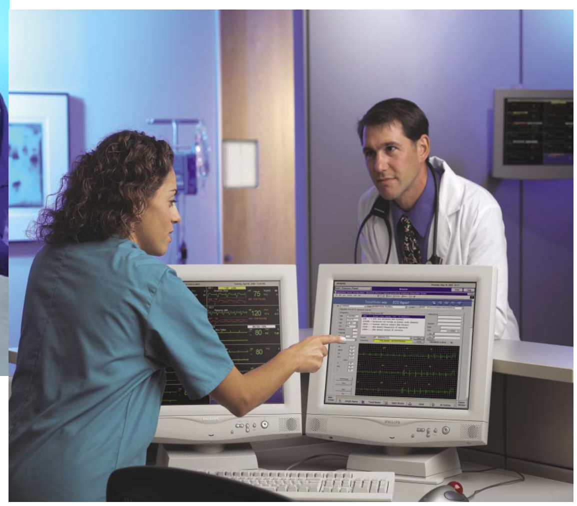
Philips provides a comprehensive ECG solution to meet both the diagnostic and monitoring needs of patients in critical care. In addition to the standard 3 or 5-lead monitoring, there are two types of 12-lead ECGs, directly acquired using a 10 leadwire set or EASI derived from a 5 leadwire set.

This solution offers both continuous 12-lead monitoring at the bedside and diagnostic 12-lead ECG capture.

The 10 seconds of captured 12-Lead ECG is analyzed using the Philips 12-lead analysis algorithm at the Information Center. For the directly acquired 12-lead, the time-based interval measurements, axis measurements and the interpretation statements are provided. For the EASI derived 12-lead only the time-based interval measurements are provided.

The captured 12-Lead ECGs can be reviewed at the Information Center as well as at the bedside using portal technology.





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12-Lead ECG at the IntelliVue Patient Monitor

At the bedside monitor, 12 leads of ECG can be viewed, recorded or printed. In addition, any two of the 12 leads of ECG can be selected for multi-lead arrhythmia analysis and all 12 leads of ECG can be used for ST segment analysis.

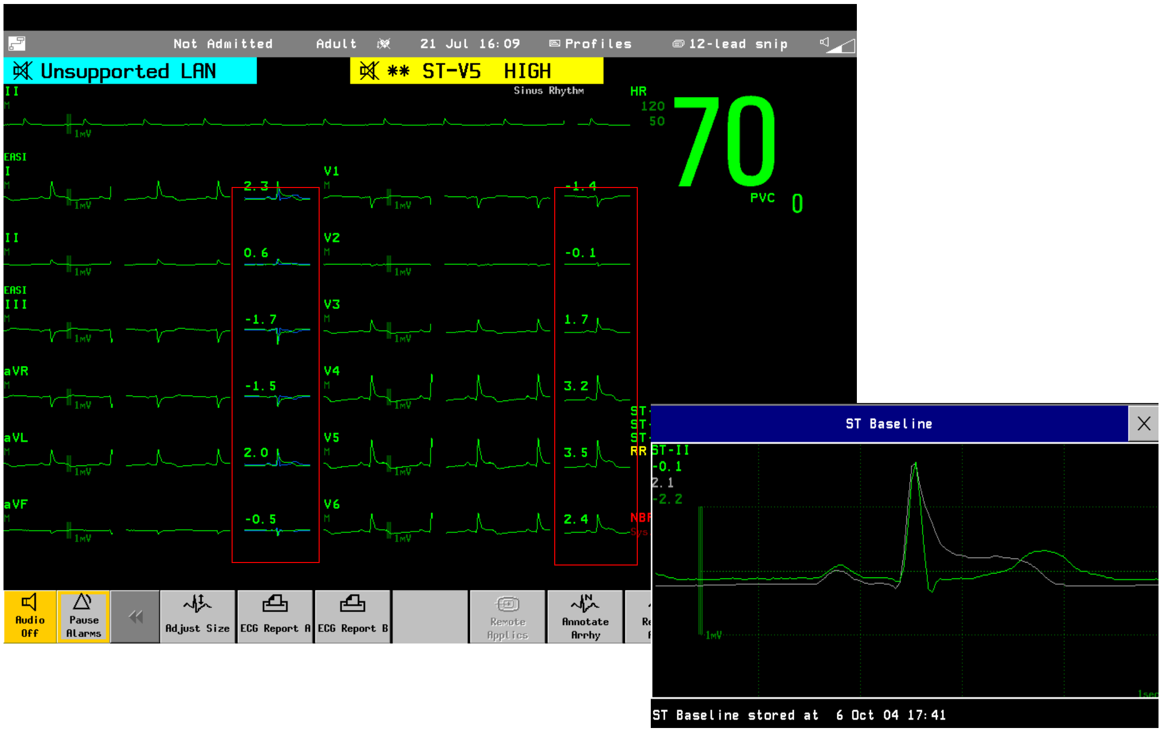

Figure 1. 12-Lead ECG screen at the IntelliVue Patient Monitor

12-Lead ECG at the Information Center

The captured 12-lead ECG can be viewed through the 12-lead Review button on the Patient Window after the completion of analysis at the IntelliVue Information Center. The Information Center can store up to 10 captured 12-lead ECGs.

In addition, the Information Center has the capability of 24 hour 12-lead ECG full disclosure when EASI lead placement is used at the bedside.

The analyzed 12-lead ECG can be sent back to the bedside monitor for review by the clinician via the Application Server and portal technology.

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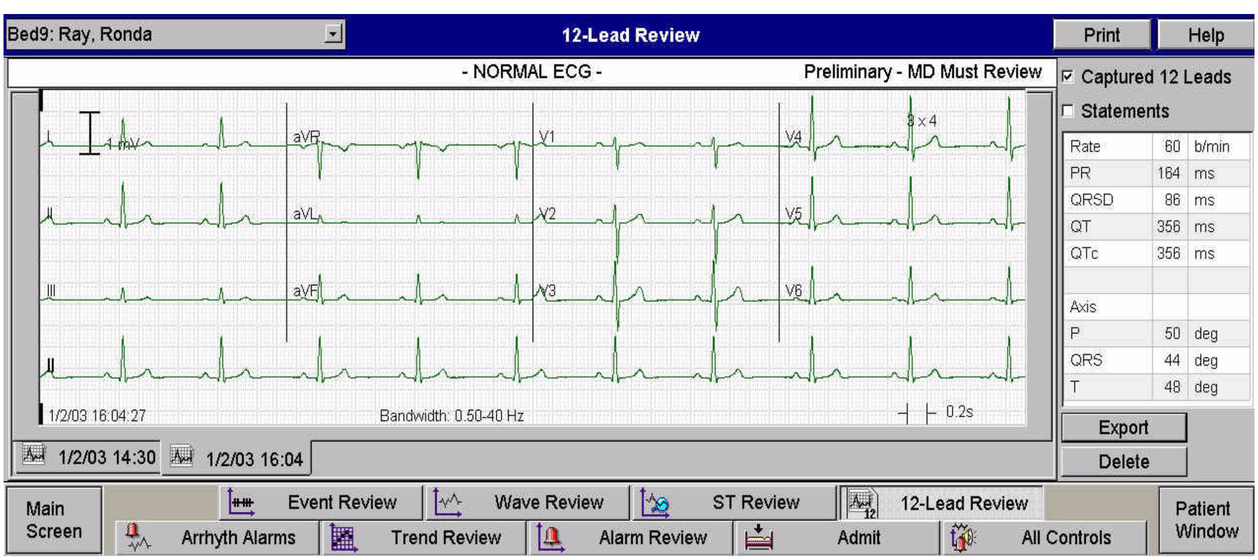


Figure 2. Information Center 12-Lead Review Window reviews captured 12-Leads from the bedside monitor

Obtaining 12-Lead ECGs

Fig. 3 demonstrates how 12-lead ECGs are obtained and transmitted across the monitoring system.

Traditionally diagnostic 12-lead ECGs are acquired using a cardiograph. The cardiograph uses a 12-lead interpretation algorithm to analyze the ECG waveforms.

The IntelliVue Patient Monitor provides the capability of monitoring up to 12-leads of ECG. This allows the clinician to view, print and record multiple leads of real-time ECG for purposes of arrhythmia and ST monitoring.

When the **Capture 12-Lead** command at the IntelliVue Patient Monitor is selected, diagnostic 12-lead ECG waveforms are sent to the Information Center for storage and analysis. The Information Center with the same 12-lead interpretation algorithm as the Philips PageWriter Touch cardiograph, analyzes the 12-lead ECG. The 12-lead ECG can then be reviewed, printed and/or exported to TracemasterVue or an ECG management system for storage and validation by a qualified clinician.

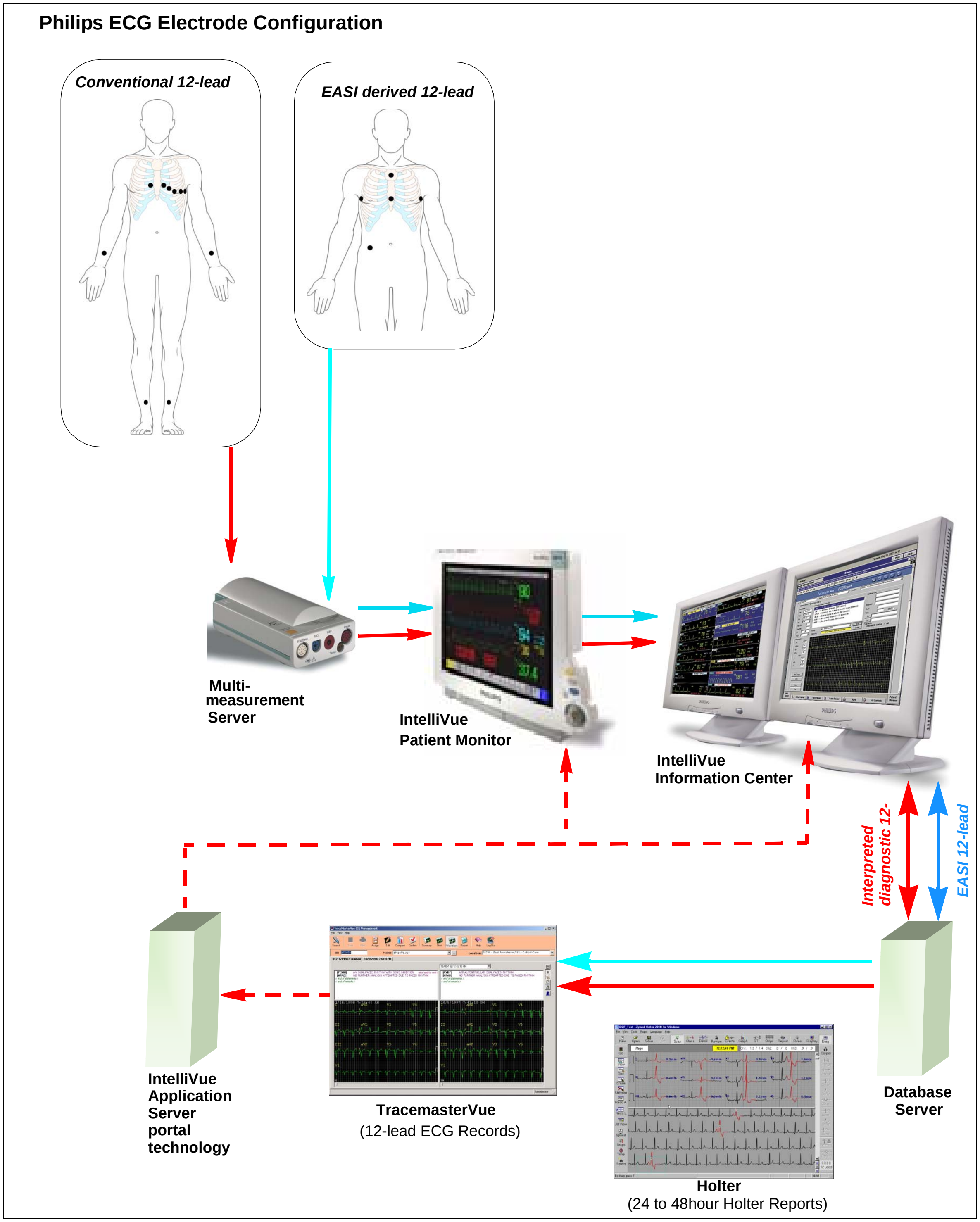


Figure 3. IntelliVue Monitoring System

12-Lead ECG Electrode Placement

Conventional Lead Placement

Limb Electrodes

- Place arm electrodes on the inside of each arm, between the wrist and the elbow.
- Place leg electrodes inside of each calf, between the knee and the ankle.
- To minimize muscle artifact, place the electrodes on the fleshy part of the limb, avoiding large bones and muscles.

Note: Bone is a poorer conductor but may produce less muscle interference. Muscle is a better conductor but may produce more interference.

Chest Electrodes

Table 1 lists the placement of the chest (precordial) electrodes. Place them in the following order:

V1, V2, V4

V3 (halfway between V2 and V4)

V6

V5 (halfway between V4 and V6)

Table 1: Placement of Chest Electrodes

Electrode	Position
V1	on the 4th intercostal space at the right sternal border
V2	on the 4th intercostal space at the left sternal border
V3	midway between the V2 and V4 electrode positions
V4	on the 5th 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

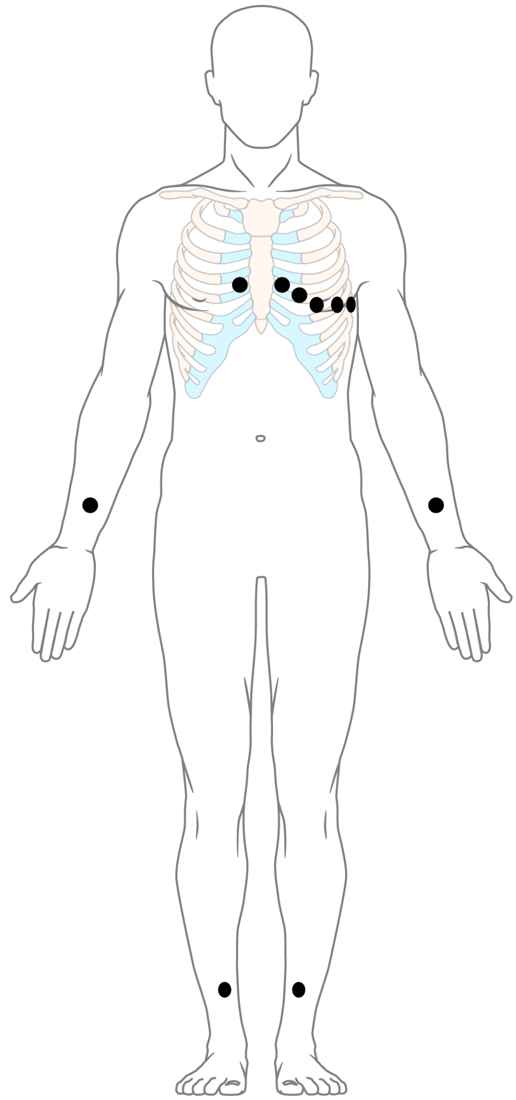


Figure 4. Conventional 12-lead Placement

Modified Lead Placement (Mason-Likar)

In the modified (Mason-Likar) electrode configuration, the limb electrodes are placed on the torso in the same locations as used for standard continuous ECG monitoring.

- The arm electrodes are placed below the clavicle near the shoulders.
- The leg electrodes are placed on the lower abdomen.

The chest (precordial) electrodes are placed in the same positions as conventional 12-lead placement.

As with conventional 12-lead placement, accurate electrode placement is required for quality 12-lead measurements.

This lead placement cannot be used for diagnostic interpretation using the Philips12-lead Algorithm.

Advantages of Modified Electrode Placement

One advantage of the Mason-Likar configuration is that it is less susceptible to movement artifact than the conventional 12-lead placement (because the limb electrodes are on the torso); however, movement artifact may still be encountered.

Also, because the electrodes are on the torso, the modified placement is more comfortable for the patient than the conventional placement.

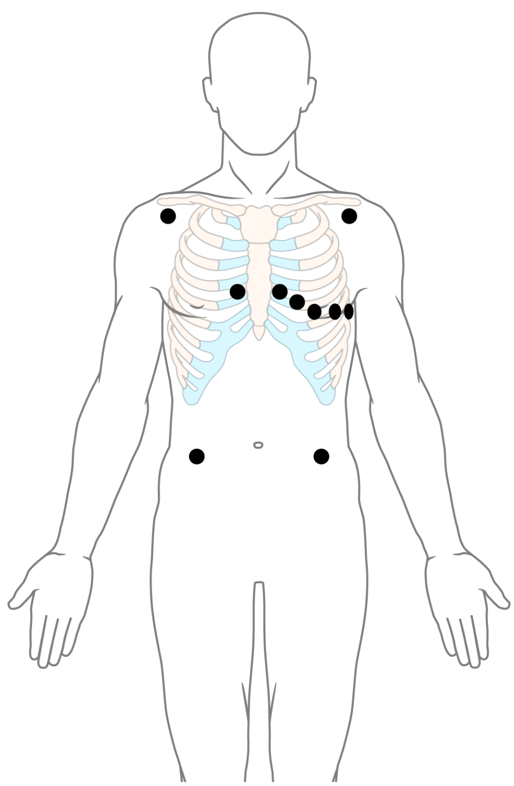


Figure 5. Modified Lead Placement (Mason-Likar)

EASI™ Lead Placement

EASI monitoring is available on the IntelliVue Patient Monitor. To monitor with EASI lead Placement, you must enable EASI in the Setup ECG menu item Lead Placement.

EASI derived 12-lead ECGs and their measurements are approximations to conventional12-lead ECGs and should not be used for diagnostic interpretations.

The Label "EASI" is shown beside the 1mV calibration bar on the ECG wave on the display, and "EASI" is marked on any recorder strip and printout.

Table 2: Placement of EASI Electrodes

Electrode	Position
E	on the lower sternum at the level of the fifth intercostal space
A	on the left midaxillary line at the same level as the E electrode
S	on the upper sternum
I	on the right midaxillary line at the same level as the E electrode
Ref	reference electrode - can be anywhere, usually below the sixth rib on the right hip

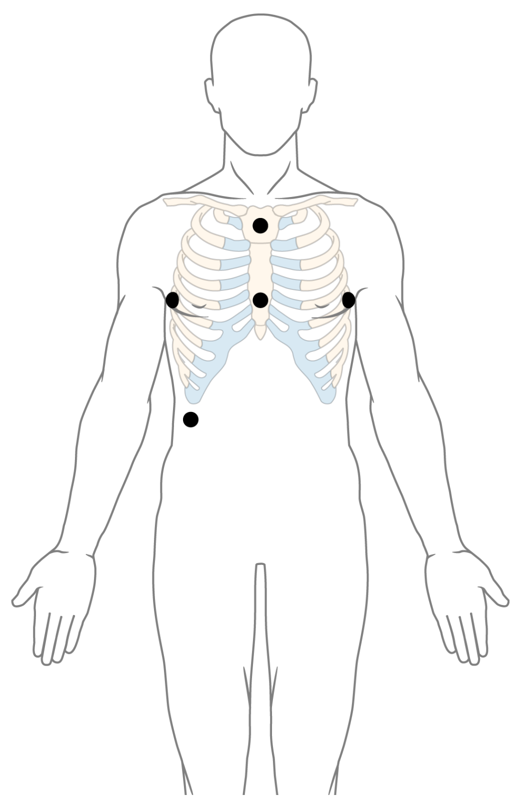


Figure 6. EASI Lead Placement

Differences between Conventional Electrode Placement and Modified Electrode Placement

To properly record a 12-lead ECG, it is important to have the patient lying comfortably with the wrist close to but not touching the trunk. The limb electrodes should be placed on the right and left wrists and the right and left ankle. The outer aspect of the wrist should be used to ensure that the arm does not need to be rotated. The leg electrodes should be placed on the outer aspect of each ankle.

In continuous 12-Lead ECG monitoring, electrodes placed in conventional lead placement, may cause excessive noise due to muscle activity and electrode artifact due to electrode movement. The signal noise caused by muscle activity can be reduced by placing the electrodes on the shoulders and hips instead of the wrists and ankle as suggested by R. E. Mason and I. Likar in 1966. The Mason-Likar modification of the 12-Lead system is used in exercise ECG and continuous bedside monitoring of the 12-lead ECG.

If the limb electrodes are placed on the thorax (Mason-Likar Placement), the recording will be different from that obtained using the conventional electrode placement (see Fig. 8). These variations include a rightward shift of the mean QRS axis due to a reduction in R wave amplitude in I and aVL, and increase in R wave in Lead II, III and aVF. Chest leads are also affected because of the altered potential of the central terminal.

There are occasions when limb electrodes need to be shifted to obtain 12-lead ECGs. For example, a cast on a limb, a missing part or the entire limb or minimize noise in the ECG signal.

Any change in electrode placement from the conventional electrode placement must be clearly noted on the ECG recording or printout. The IntelliVue Patient Monitors allows the user to mark the printouts and captured 12-leads ECGs as a modified lead placement. In the ECG setup window, Mod. LeadPlacement - On, labels all 12-lead reports and captured 12-lead ECGs from the bedside to the Information Center as Mason Likar (see Fig.8).

Be sure to mark ECGs as modified (Mason-Likar) to prevent misdiagnosis and use caution when comparing 12-lead ECGs acquired using different electrode placements.

The 12-lead ECGs displayed on the following page demonstrate the changes that occur when placing the limb electrodes in different positions. All three 12-lead ECGs were obtained from the same individual.

In Fig. 7, the limb electrodes were placed on the outer aspect of the wrist and ankles. In Fig. 8, the limb electrodes were moved to the body trunk which is typically the position of the limb electrodes during continuous monitoring. This 12-lead ECG shows significant changes in the limb leads particularly in Leads II, III and aVF. The P-wave, QRS and T-wave axis measurements also demonstrate large differences from the 12-lead ECG performed with the limb electrodes on the wrists/arms and ankles/leg. In addition, the 12-lead ECG interpretative algorithm based on these measurements interpreted this 12-lead ECG as a “borderline right axis deviation.”

These differences that the modified lead placement creates may lead to misdiagnosis and may mask inferior infarction due to calculated axis, R-, P- and T-wave magnitudes shifts, and ST slope.

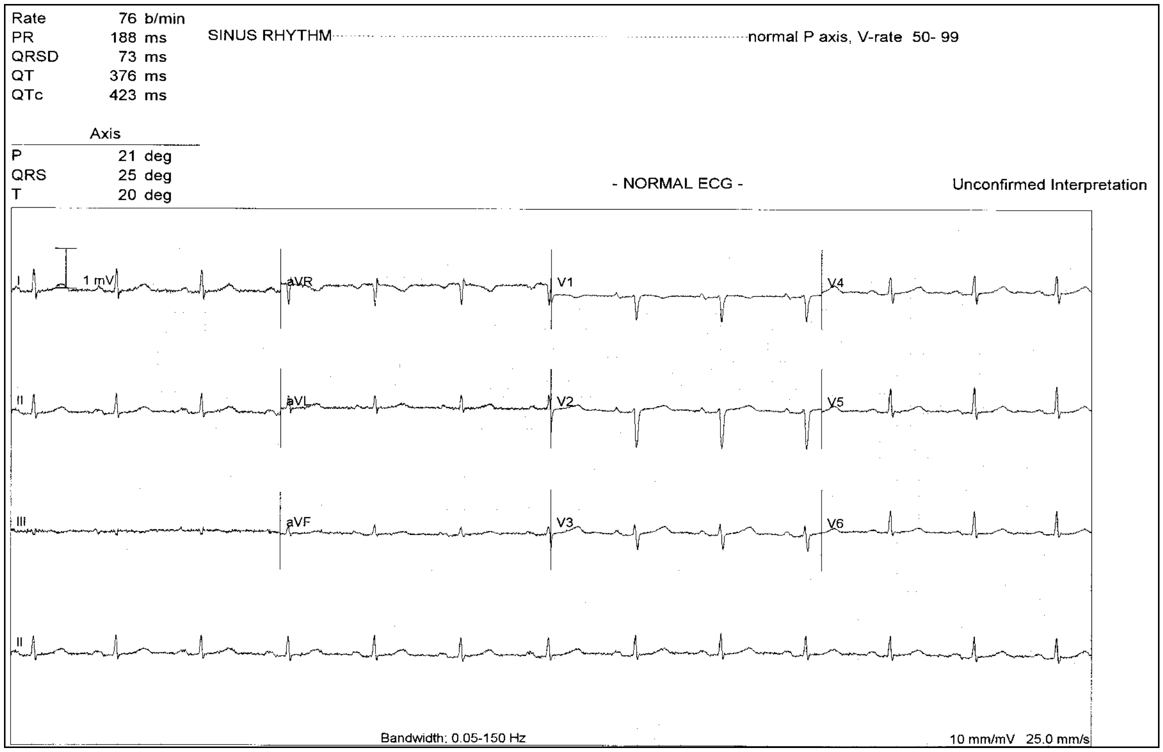


Figure 7. Conventional Lead Placement - Limb electrodes on the wrists and ankles

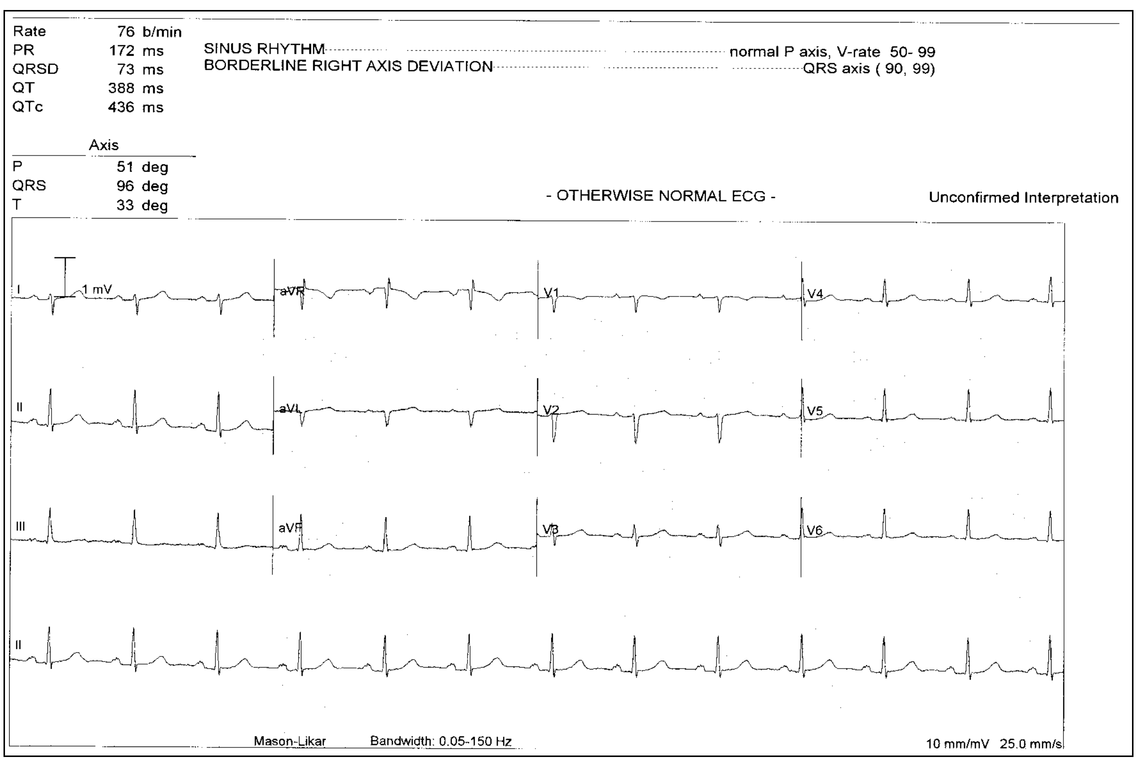


Figure 8. Modified Lead Placement (Mason-Likar)

Checking for Correct Placement

To ensure quality 12-lead monitoring, it is important to check that the electrodes are correctly placed. If they are, you should see these landmarks (as shown in Fig. 9).

- Positive P-wave in Lead II.
- Negative QRS in Lead aVR.
- R-wave progression in the precordial leads. Normal R-wave progression is as follows:
  - Negative R-wave in V1 and V2.
  - Biphasic R-wave in V3.
  - Positive R-wave in V4 - V6

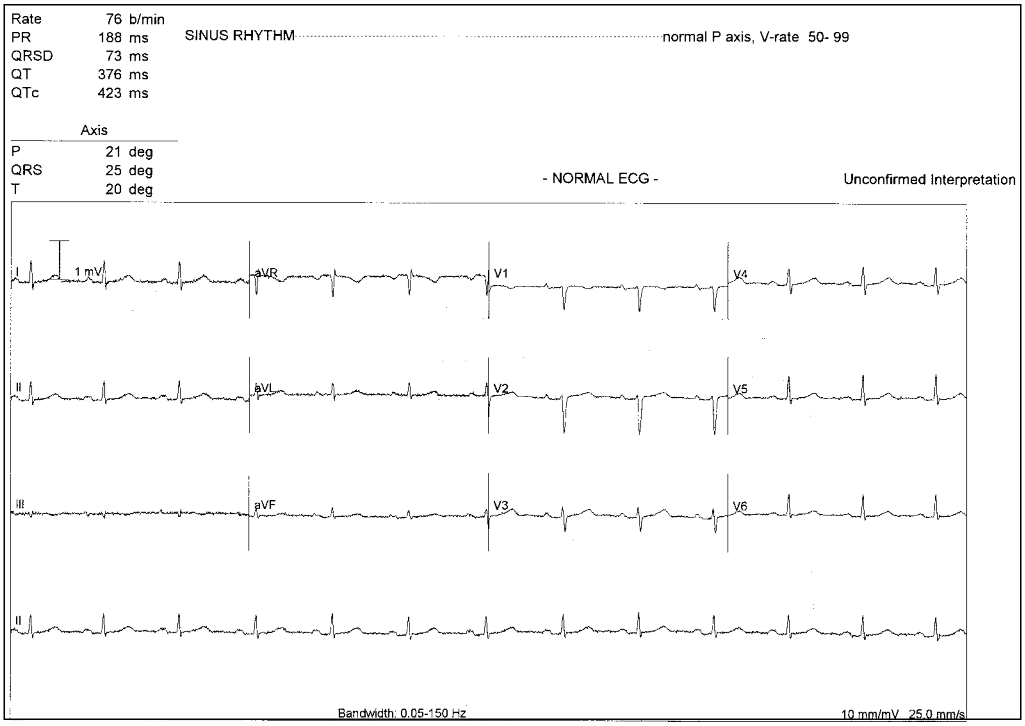


Figure 9. Correct Lead Placement

In Fig.10, the right and left arm electrodes have been reversed - all other lead placement is correct. By noting that aVR is positive, the 12-lead ECG analysis algorithm was able to detect this error and alert the clinician to repeat the 12-lead ECG.

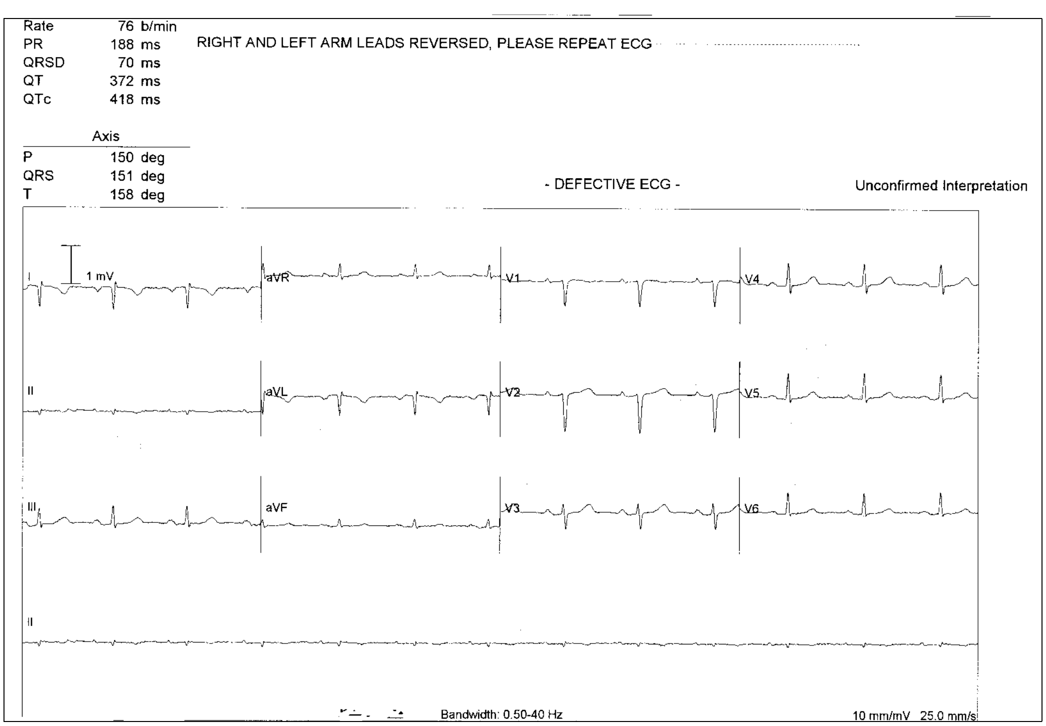


Figure 10. Incorrect Lead Placement - Reversed right and left am electrodes

Signal Processing

The ECG signal at the body surface is transmitted via the ECG leadset and cable. The ECG measurement device then digitizes the analog signal at a sample rate of 500 samples per second in the frequency range of 0.05 Hz to 150 Hz.

Filter Settings Selection at the Bedside

These filters suppress ECG signals at the high and low frequency range to allow the user to view a clearer ECG signal when noise is present.

The following table lists the different bandwidths that result from applying the different filter modes available the IntelliVue Patient Monitors.

Adult Patient Category
Diagnostic Mode: 0.05 - 150 Hz Monitoring Mode: 0.5 - 40 Hz Filter Mode: 0.5 - 20 Hz
Pediatric/Neonatal Patient Category
Diagnostic Mode: 0.5 - 150 Hz Monitoring Mode: 0.5 - 55 Hz Filter Mode: 0.5 - 20 Hz

To obtain an ECG signal with the highest fidelity for viewing, recording and printing use the Diagnostic Mode in the adult patient category.

Using Filters

There is a trade off between clarity and fidelity of the ECG trace when a filter is applied. The more filtering applied, the greater the possibility of removing ECG signal details.

Changing the high frequency filter to 20, 40 or 55 Hz results in a smoother looking ECG waveform while eliminating some fine detail in the signal. Small deflection, notches, slurs may be distorted or may disappear if one of these filters is applied.

Changing the low frequency filter to 0.5 Hz can be used to reduce baseline noise such as baseline wander. Baseline wander is the slow (typically 0.1 - 0.2 Hz) drifting of the ECG baseline up or down. Baseline wander may result from patient respiration or from other sources such as dried electrodes. Severe baseline wander may make it difficult to determine the true wave shapes in the ECG.

The disadvantage of the low frequency filter change is that it will result in ST Segment distortion in the displayed, recorded or printed ECG waveforms.

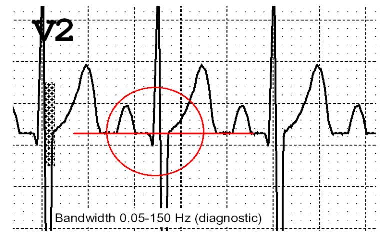


Figure 11. Diagnostic Mode 0.05 Hz - no ST distortion

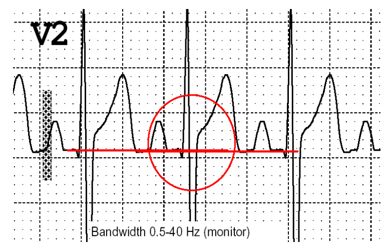


Figure 12. Monitor Mode 0.5Hz - ST distortion

Filter settings used for ST Segment Analysis

The ST/AR ST analysis algorithm receives the ECG signal at the highest fidelity 0.05 Hz regardless of the patient category or filter mode setting. ST/AR applies a special 0.67 Hz filter for analysis. This filter type does not distort the ST segments.

The ST waveforms captured by the ST/AR analysis algorithm can be used for assessment of ST segment changes (Fig.13). The ST waveforms can be displayed at the bedside as well as recorded. The ST waveforms are also stored at the Information Center for the ST Review application.

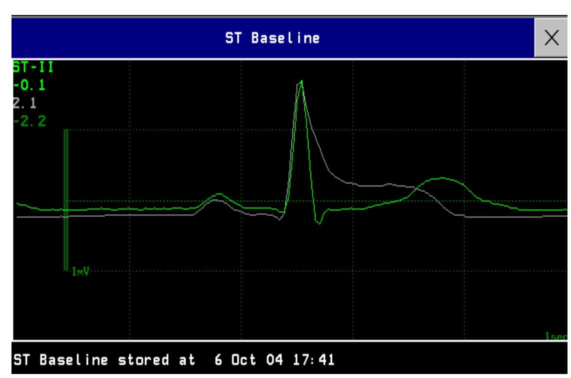


Figure 13. ST snippets available on the IntelliVue Patient Monitor can be used for assessment

Filters used for 12-Lead Captures

The 12-Lead ECG signal sent from the bedside is at a sample rate of 500 samples per second in the frequency range 0.05 Hz to 150 Hz. This signal is used for the 12-Lead ECG analysis performed by the Philips 12-Lead Algorithm.

For viewing and printing, the 12-Lead ECG will be filtered using the bandwidth selected at the bedside. Although the bandwidth at the Information Center is the same as the bedside, the filter type is not the same.

The type of filter used by cardiographs and 12-lead ECG capture programs is a filter that does not cause distortion of the ST segment when using 0.5 Hz filter. However it requires delayed processing and cannot be used when real-time viewing and recording is required.

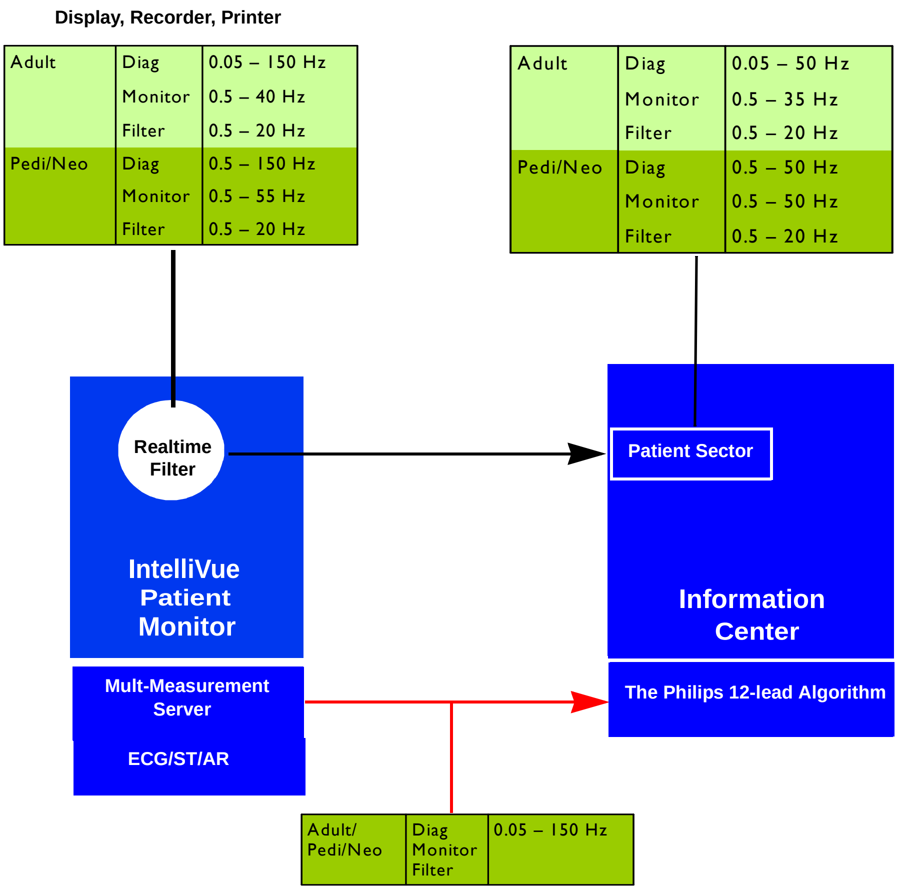


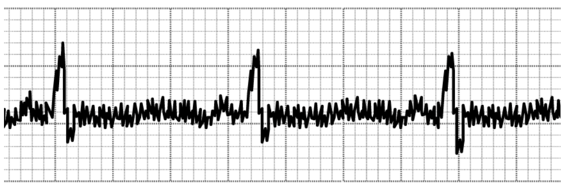
Figure 14. 12-Lead ECG capture

Common 12-Lead ECG Monitoring Problems

Obtaining a 12-lead ECG with computer-assisted ECG analysis begins by obtaining accurate and noise-free ECG waveforms. Improving the electrode to skin interface by preparing the skin and using fresh electrodes helps eliminate most noise quality problems.

This section describes common problems that can be encountered when using both conventional and modified electrode placement.

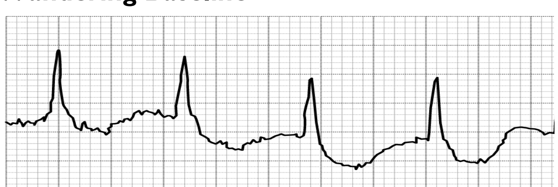
Electrical Interference



Possible cause: Presence nearby from an electrical device (e.g., IV pump, microwave oven, cellular phone).

Solution: Check the environment for possible electrical devices that can cause interference and unplug if possible or switch the device to battery power.

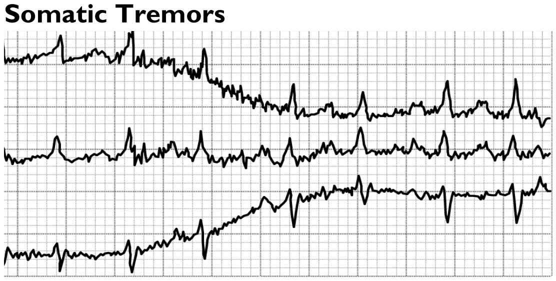
Wandering Baseline



Possible cause: Patient movement, respirations, dry electrodes or loose electrode.

Solution: Instruct the patient to lie quietly. Apply fresh electrodes.

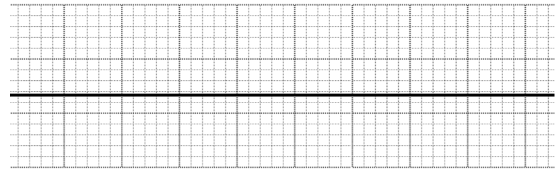
Somatic Tremors



Possible cause: Involuntary movement (shivering).

Solution: Warm/cover the patient and assist with limiting patient movement.

Loose Electrode



Possible cause: Electrode is not adhering adequately to the skin.

Solution: Check electrodes and re-apply if needed.

The Philips 12-Lead Analysis Algorithm

For the conventional 12-lead ECG waveforms provided by the IntelliVue Patient Monitor, the Philips 12-Lead algorithm provides an analysis of the amplitudes, durations and morphologies of the ECG waveforms and the associated rhythm. For the EASI 12-Lead ECG, the Philips 12-Lead algorithm provides only time-based interval measurements.

The ECG analysis is based on standard criteria for interpretation of these parameters, calculation of the electrical axis and the relationship between leads.

The algorithm is highly age and gender specific. Patient age and gender are used throughout the program to define normal limits for heart rate, axis deviation, time intervals, and voltage values for interpretation accuracy in tachycardia, bradycardia, prolongation or shortening of PR and QT intervals, hypertrophy, early repolarization, and myocardial infarction.

Adult criteria apply if the patient age entered is 16 years old or older or if no age is specified. Pediatric criteria apply if the patient age entered is younger than 16 years of age.

Keep in mind that a computer-interpreted ECG report is not intended to be a substitute for interpretation by a qualified clinician. The interpreted ECG is a tool to assist the clinician in making a clinical diagnosis in conjunction with the clinician's knowledge of the patient, the results of physical examination, and other findings. The algorithm helps to identify problem areas for the clinician and saves time for the clinician or editing technician who may need only to add, delete or modify a few statements.

The 12-Lead Analysis Algorithm Process

The following is a brief review of the Philips 12-Lead Algorithm. For a detailed description of the 12-Lead Algorithm, review the Philips 12-Lead Algorithm Physician's Guide (Part# M5000-91000).

Step 1 Signal Quality Check

The algorithm examines the signal quality of each ECG Lead to ensure that good ECG measurements can be made. The ECG is analyzed for muscle artifact, AC noise, baseline wander, and leads off. In addition, a check for correct placement of right arm and left arm leads is also performed. Any problems that are not corrected by the operator are described in the interpretative statements on the ECG report.

Step 2 Waveform Recognition

This step involves beat detection and waveform recognition. If paced mode is on, pacing spikes detected at the bedside monitor are used for analysis. Pacer spikes are then removed and the resulting waveforms are analyzed with a boundary indicator derived from all leads. Subsequently approximate P wave, QRS complex and T wave regions are then determined for each beat in the ECG.

Step 3 Measurements

Once the final onsets and offsets are determined, the amplitude, duration, area and shape are calculated for every P- wave, QRS complex, ST segment and T-wave in each lead. Waveform irregularities such as notches, slurs, delta waves and pacemaker spikes are also noted for every beat.

Measurements for each of the 12 leads are calculated from the predominant beat type. Only if all beats in the ECG are classified as ventricularly paced will the measurements be performed on the paced beats. If an ECG contains both paced and non-paced beats, only non-paced beats will be measured.

Atrial Rhythm analysis is determined by examining leads V_1, aVF, II and III in succession until the algorithm can determine the number of P waves per QRS complex. If the determination fails, no atrial rhythm parameter is calculated.

Axis Measurements

Instead of using the waveform amplitudes, the waveform areas are used to calculate P, QRS and T axis measurements for more accurate results. The sum of the ST onset, middle and end amplitudes is used in calculating the ST axis.

The frontal plane axis measurements use the six limb leads to estimate the axis. The horizontal plane axis measurements are calculated from leads V_1-V_6.

Step 4 Interpretation

Based on waveforms and measurements the final diagnostic interpretation is performed. Each diagnostic category may be represented by only one statement in the final report. This statement is the most specific one encountered whose medical criteria were true based on the measurements, earlier decisions, and patient information (gender and age).

Overall Serverity

Each interpretative statement selected for the ECG report has an associated serverity. The serverities associated with these statements are then combined to determine the overall serverity for the 12-Lead ECG report.

12-Lead ECG Reports

There are two type of 12-Lead ECG reports available:

- Real-time 12-lead ECG reports requested at the IntelliVue Patient Monitor
- Captured 12-Lead ECG printed from the Information Center 12-Lead Review application.

12-Lead ECG reports are available in several configurable formats and layouts.

Formats

- 3 x 4 landscape (Fig. 15)
- 6 x 2 landscape (Fig.17)
- 12 x 1 portrait (Fig.16)

At the Information Center the 3 x 4 format, the most commonly selected format, shows consecutive 2.5 second segments of the12-lead, three leads at a time with a 10 second continuous rhythm strip displayed at the bottom of the report.

Bedside monitor real-time 12-lead reports are formatted in the same way except that the 2.5 second segments are simultaneously obtained.

The 6 x 2 format and 12 x 1 formats show longer waveform segments in multiple leads that may be more suitable for reviewing arrhythmias.

Layouts

There are two configurable limb lead layouts for printed 12-lead reports.

- International
  - I, II, III, aVR, aVL, aVF
- Cabrera
  - aVL, I, -aVR, II, aVF, IIII

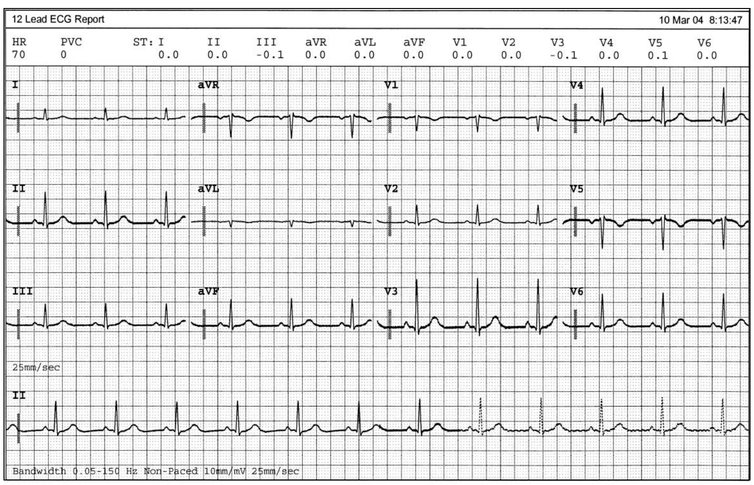


Figure 15. IntelliVue Patient Monitor 12-Lead ECG in 3 x 4 format

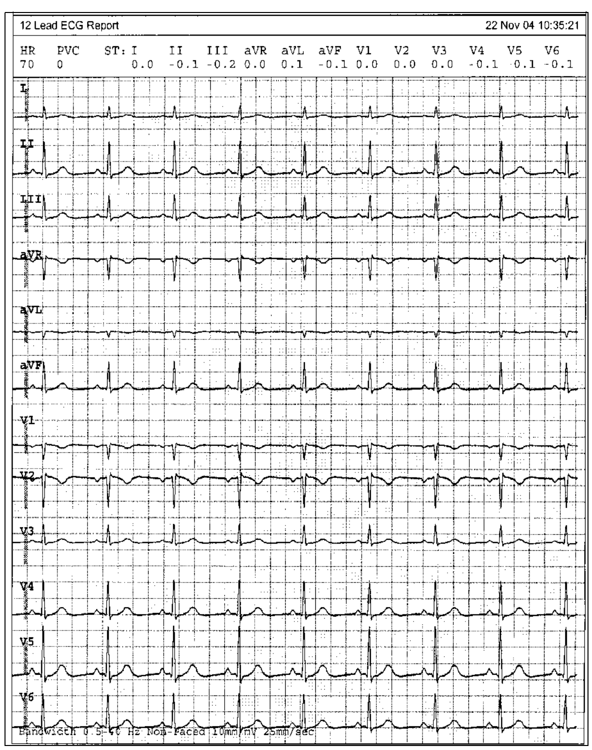


Figure 16. IntelliVue Patient Monitor 12-Lead ECG in 12 x 1 format

IntelliVue Real-time 12-Lead ECG Report

A typical IntelliVue Patient Monitor12-Lead ECG report is shown below (Fig.17). It is important to remember that real-time reports use real-time filters which may cause ST distortion if the filter mode selected has a 0.5 Hz low frequency filter.

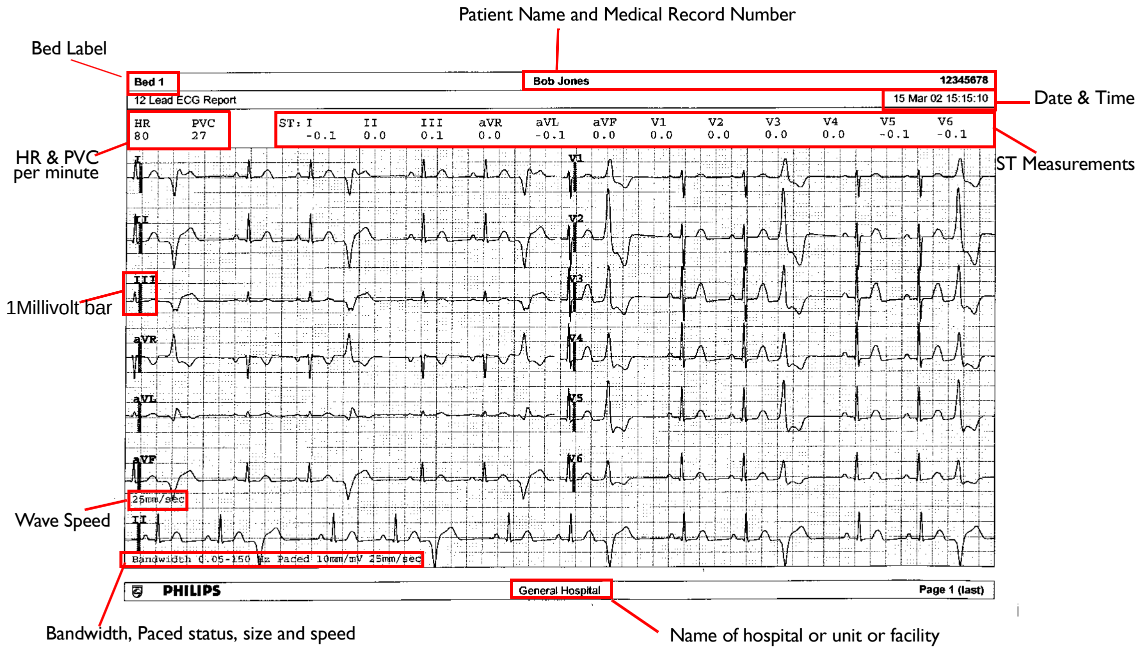


Figure 17. IntelliVue Patient Monitor 12-Lead ECG Report, 6 X 2 Format

Field	Notes
Bed Label	This is identical to the label displayed in the Monitor Info Line on the bedside monitor. If the monitor is connected to an Information Center, the label is controlled by the central station. If the bedside monitor is not connected to a central station, the label is the configured equipment label.
Patient Name & Medical Record Number	The Patient Name and ID will appear on the report only if this information has been entered in the Patient Demographics Window.
Date & Time	Date and Time will always appear on the report.
HR & PVC per minute	This is the HR and PVC count which is displayed at the time of the report.
ST Measurements	ST measurements will appear on the 12-Lead report if the ST analysis is turned on. These measurements are generated from the ST/AR ST analysis.
MilliVolt bar	The calibration pulse is the rectangular waveform shown on the first line of the ECG trace. It shows how much the cardiograph deflected the trace in response to a 1 mV calibration pulse applied to the acquisition circuitry. The milliVolt Bar is a visual indicator of Size.
Wave Speed	The wave speed is adjusted in MainSetup >Reports > ECG Reports > Speed.
Bandwidth, Paced Mode, Size and Speed	The bandwidth is set in the Setup ECG > Filter. If contour analysis is important use Diagnostic mode which minimizes the ST Segment distortion. Paced Mode can be changed in the Setup ECG menu, Patient Demographics window, or Profiles menu.
Name	The hospital or institution name or unit name if configured in the IntelliVue Patient Monitor.

Information Center Captured 12-Lead ECG Reports

A typical 12-Lead ECG report using conventional lead placement obtained from the Information center is shown below in Fig.18. It contains basic measurements, interpretative and severity statements, and status information.

A 12-Lead ECG report obtained using EASI lead placement and setup at the IntelliVue Patient Monitor as EASI Lead placement will be labelled on the report as EASI. The 12-lead ECG capture labelled as EASI will only contain time based basic measurements.

If the user has placed the electrodes in modified electrode placement (Mason-Likar) and has set bedside to **Mod.LeadPlacement**: On, the 12-lead ECG report will be marked "Mason Likar".

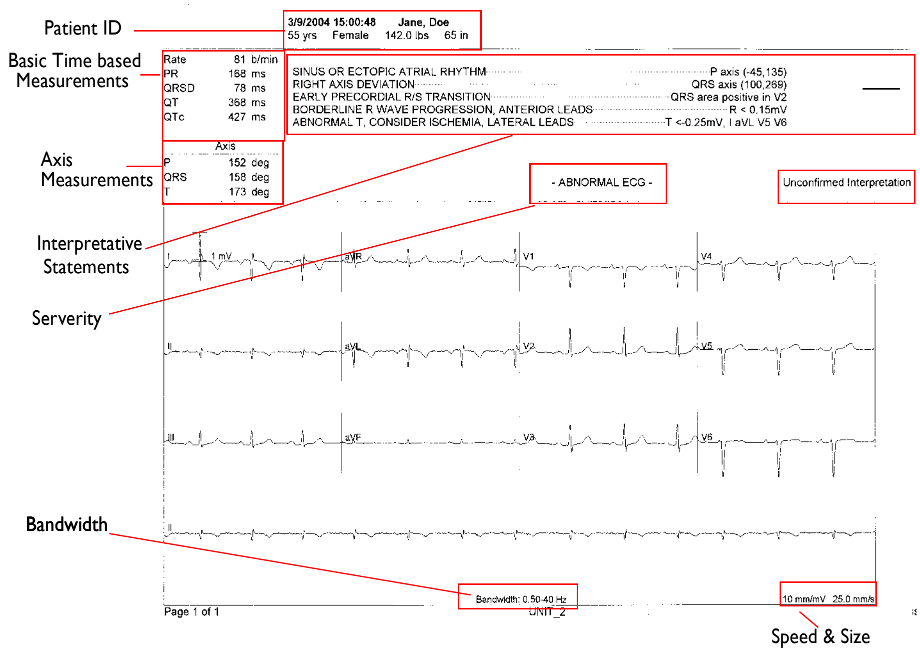


Figure 18. 12-Lead Report from the Information Center

Field	Notes
Patient ID Information	This section contains the date and time the report was generated and the patient identification information.
Basic Measurements	This section provides the heart rate, the standard interval and duration measurements, and limb lead axis measurements. These are representative values for the dominant beat pattern in the ECG.
Interpretive and Reason Statements	This section contains the interpretive statements and the reason statements generated by the Philips 12-Lead Algorithm.The interpretive statements (for example: `SINUS RHYTHM`) are listed at the left of the section in uppercase letters. Interpretive statements can also include a reason statement that summarizes the conditions that generated the interpretive statement (for example: `normal P axis, V-rate 50-99`). Interpretive statements can include quality statements that describe a signal quality problem that occurred during the recording, such as: `ARTIFACT IN LEAD(S) I, III, aVL`.
Severity Statement	The severity statement represents the overall severity of the ECG.
Status of Report	The status of the report from the Information Center will be unconfirmed. This indicates that the ECG report has not been overread by a qualified physician. The 12-Lead ECG status can be changed once the ECG has been exported to a 12-Lead Management system.
Calibration Information	The calibration pulse is the rectangular waveform shown on the first line of the ECG trace. It shows how much the cardiograph deflected the trace in response to a 1 mV calibration pulse applied to the acquisition circuitry.
Bandwidth Information	The 12-Lead ECG capture is transmitted to Information Center in diagnostic bandwidth (0.05=150 Hz). The 12-Lead ECG is *analyzed* using this bandwidth. It is *displayed* using the bandwidth settings from the bedside monitor. As the bedside monitor bandwidth settings are applied to the 12-Lead not as a real-time filter but in a manner which minimizes the distortion of the ST segment.
Speed and Size	Speed and Size are changeable.

Summary

Monitoring 12-leads of ECG simultaneously at the patient bedside monitor improves the clinician's ability to monitor and trend arrhythmias and ST changes as well as record a diagnostic 12-lead ECG.

The IntelliVue Patient Monitor provides the user with:

- Screens to view all 12-leads of ECG as real-time waves in either monitor or diagnostic modes.
- Recordings of ECG waveforms for documentation.
- Printed reports in various formats for documentation.
- Printed reports in either monitor mode or diagnostic mode providing either a 12-lead ECG monitoring report or a 12-lead ECG diagnostic report.
- A captured diagnostic 12-lead ECG sent to the Information Center for analysis and interpretation.

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Printed in The Netherland
4522 981 97801/862 2005 January