# 12-Lead ECG Monitoring

**ZOLL** **M**Series

This issue date or revision level for this operation guide is shown on the front cover.
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# 12-LEAD ECG MONITORING

⊣|♥|⊢ ECG leads are a defibrillation protected Type CF patient connection.

# General Information

## Product Description

ZOLL **M Series** with 12-Lead option provides simultaneous 12-lead ECG acquisition, storage, display, transmission, and optional ECG analysis using the GE Medical Systems Information Technologies 12SL$^{TM}$ Analysis Program. 12SL is a trademark of GE Medical Systems.

ZOLL **M Series** with 12-Lead and Catalyst™ MUSE® interface option allows for direct transmission of 12-lead ECG records to a GE Medical Systems Catalyst MUSE system. The Catalyst MUSE system provides access to online patient ECG records and enables physicians to quickly view and compare prehospital or hospital 12-lead data. Catalyst MUSE is a trademark of GE Medical Systems.

### Intended Use

The ZOLL **M Series** with 12SL is intended for the recording and automated analysis of 12-lead ECG signals acquired from adult and pediatric patients in the supine, resting position.

### Indications for 12-Lead Analysis Use

The 12-lead ECG Analysis is useful in the diagnosis and treatment of patients with acute myocardial infarction (AMI). 12-lead ECG Analysis is also useful in the interpretation and documentation of other transient cardiac arrhythmias that may occur. When used in the prehospital setting, the 12-lead analysis results can be of assistance in diagnosis and treatment decisions once the patient has arrived in the hospital emergency department.

## How to Use This Manual

This manual provides instructions for using the ZOLL **M Series** with 12-Lead option.  It does not contain information on how to read or interpret electrocardiograms (ECGs). It covers the following:

- **Warnings**
- **Electrode Placement**
- **12-Lead Acquisition**
- **12-Lead ECG Data Transmission**
- **12-Lead Reports**
- **Daily Operational Verification**
- **Troubleshooting**

# WARNINGS

- Before use, carefully read the **M Series** Operator's Guide and these operating instructions.

- The **M Series** with 12SL is designed to acquire and interpret ECG data from resting, supine patients. Use of the device to acquire ECG signals from moving or shaking patients may produce erroneous 12-lead interpretation results. Always ensure that the patient is kept motionless during 12-lead ECG signal acquisition and analyses.

- The **M Series** 12SL option is not intended for use with neonatal patients.

- Excessive body hair or wet, sweaty skin may interfere with electrode adhesion. Remove the hair and/or moisture from the area where the electrode is to be attached.

- Using previously opened or out of date electrodes may degrade the ECG signal quality. ECG electrodes should be removed from their sealed package immediately prior to use.

- Monitoring electrodes may become polarized during defibrillator discharge, causing the ECG waveform to briefly go off screen. ZOLL Medical Corporation recommends the use of high quality silver/ silver chloride (Ag/AgCl) electrodes to minimize this effect, and circuitry in the instrument will return the trace to the monitor display within a few seconds.

- Wait 15 seconds after defibrillator discharge before attempting a 12-lead acquisition. Electrode polarization subsequent to defibrillator discharge may result in excessive noise on the 12-lead ECG printout.

- Cover the patient cable's V-lead connector with the plastic cap supplied when the V-leads are not in use. Failure to do so may result in a shock hazard during defibrillation attempts.

- To assure protection against the effects of defibrillator discharge, use only 12-lead cables supplied by ZOLL Medical Corporation.

- To avoid a shock hazard and interference from nearby electrical equipment, keep electrodes and patient cables away from grounded metal and other electrical equipment.

- Do **NOT** sterilize the **M Series** unit or any of its accessories except internal handles or as directed.

- Check the operation and integrity of the **M Series** and 12-lead cable regularly by performing the Daily Operational Verification Test.

- All computerized ECG analysis results must be reviewed by a physician prior to their use for determining patient treatment.

- Grounding reliability can ONLY be achieved when the equipment is connected to an equivalent receptacle marked "HOSPITAL ONLY" or "HOSPITAL GRADE".

- The frequency response of the monitor screen is intended only for basic ECG rhythm identification; it does not provide the resolution required for diagnostic and ST segment interpretation. Use the strip chart recorder for this purpose.

- Implanted pacemakers may cause the heart rate meter to count the pacemaker rate during incidents of cardiac arrest or other arrhythmias. Pacemaker patients should be carefully observed. Check the patient's pulse; do not rely solely on heart rate meters. Dedicated pacemaker detection circuitry may not detect all implanted pacemaker spikes. Patient history and physical exam are important in determining the presence of an implanted pacemaker.

## Electrode Placement

| Location | AHA Labels | IEC Labels |
|----------|-----------|-----------|
| Right Arm | RA (white) | R (red) |
| Left Arm | LA (black) | L (yellow) |
| Right Leg | RL (green) | N (black) |
| Left Leg | LL (red) | F (green) |
| Chest | V1 | C1 |
| Chest | V2 | C2 |
| Chest | V3 | C3 |
| Chest | V4 | C4 |
| Chest | V5 | C5 |
| Chest | V6 | C6 |

Place electrodes on the patient. All electrodes must be connected. Proper skin preparation and use of proper electrodes are very important for a good signal quality. If necessary prepare the patient's skin for electrode application by:

- Shaving or clipping excess hair at electrode site. Avoid placing electrodes over tendons and major muscle masses.
- Cleaning oily skin with an alcohol pad.
- Briskly rubbing site to dry.

When acquiring 12-lead ECG from quiet supine patients, ZOLL recommends placing the limb electrodes anywhere along the ankles and wrists. When it is difficult for the patient to remain motionless due to shivering, muscle tremors, or transport vehicle movement, better results are often obtained if limb electrodes are placed on the patient's thorax. (Refer to the two diagrams below for limb electrode placement).
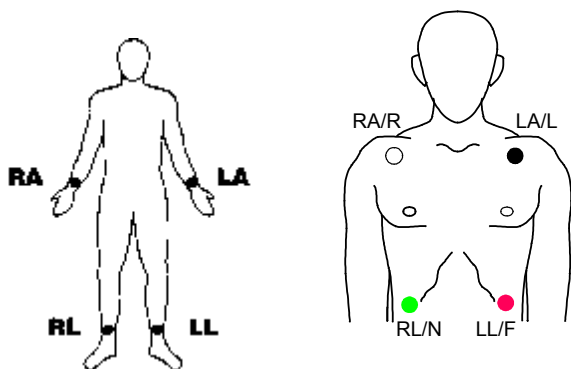
Place the precordial electrodes across the chest in the following locations:

V1 : Fourth intercostal space, at the right sternal margin.
V2 : Fourth intercostal space, at the left sternal margin.
V3 : Fifth rib, between leads V2 and V4.
V4 : Fifth intercostal space, on the left midclavicular line.
V5 : Left anterior axillary line, at the horizontal level of V4.
V6 : Left midaxillary line, at the same horizontal level as V4 and V5.

Locating the V1 position (fourth intercostal space) is critically important because it is the reference point for locating the placement of the remaining V leads. To locate the V1 position:

1. Place your finger on top of the jugular notch (see figure below).

2. Move your finger slowly downward about 1.5 inches (3.8 centimeters) until you feel a slight horizontal ridge or elevation. This is the "Angle of Louis" where the manubrium joins the body of the sternum.
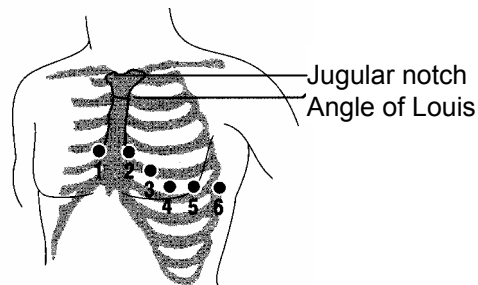


3. Locate the second intercostals space on the right side, lateral to and just below the Angle of Louis.

4. Move your finger down two more intercostal spaces to the fourth intercostal space which is the V1 position.

**Note:** When placing electrodes on female patients, always place leads V3-V6 under the breast rather than on the breast.

## 12-LEAD ACQUISITION

- Attach the electrodes to the patient (Refer to the "Electrode Placement" Section).

- Attach the 12-lead cable lead wires to the electrodes on the patient.

- Attach the V-lead cable to the 12-lead ECG cable. (When V-leads are not in use, ensure the V-leads protective cap is plugged into the V-lead connector.)

- Attach the 12-lead cable to the rear of the **M Series** product.

- Cable Dress:  Arrange the 12-lead cable such that it is neat and not dangling or looped.  Assure that the cable is not pulling on individual electrodes.

- Turn the selector switch to MONITOR mode.

- If "PADS" or "PADDLES" are selected, select Lead I. (Leads must be selected to obtain a 12-lead printout.)

- To print a 12-lead report ONLY, press and hold the **RECORDER** button for 3 seconds. The unit will begin printout of the 12-lead report.   This report consists of ten seconds of 12-lead ECG data printed in four staggered 2.5 second segments.

- To transmit the 12-lead report to a fax machine or Catalyst MUSE system, see the "12-Lead ECG Data Transmission" section below.

- The default bandwidth for 12-lead ECG data is 0.05 to 150 Hz.  An alternate bandwidth of 0.05 to 40 Hz is selectable by the user if excessive muscle or other artifact is present during 12-lead recording.  Refer to the "Filter Settings" section for instructions on how to select this configuration.

### PHYSIOLOGICAL MONITORING

When the **M Series** device is turned to **MONITOR** mode, the physiological monitoring menu will be displayed with the following softkeys:  **Param**, **Wave2**, **ID#**, **Alarms** and **12 Lead**.



If the user enters 12-lead Monitoring with two (2) waveforms displayed, the waveforms will remain displayed on the screen during 12-lead Monitoring. Pressing the **Wave 2** softkey removes the second waveform prior to entering 12-lead Monitor mode.

For AED units, the 12 Lead softkey is the third from the left.

### 12 Lead Softkey

When the **12 Lead** softkey is pressed, the following screen will be displayed.



### Acquire Softkey

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**WARNING**

All computerized ECG analysis results must be reviewed by a physician before they are used to determine patient treatment.

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The ZOLL **M Series** begins pre-acquisition of 12-lead data when the electrodes are attached to the patient.

Pressing the **Acquire** softkey causes the **M Series** to begin sequencing through the necessary steps to produce a formatted ECG recording and 12SL analysis. The message "ACQUIRING ECG" displays and the **Acquire** softkey changes to **Halt**.



Pressing the **Halt** softkey during acquisition stops the data collection process, displays an "ACQUISITION HALTED" message and changes the leftmost softkey back to **Acquire**.

During the data acquisition phase, the unit will perform a lead status check to ensure all leads are properly connected and 10 seconds of valid data have been acquired.

If one or more of the V-leads are not properly attached to the patient, a "VX LEAD OFF" message will be displayed on the screen ("VX" will indicate the specific V-lead(s) that is not attached to the patient).

If one or more of the limb leads are not properly attached to the patient, an "ECG LEAD OFF" message will be displayed on the screen and a dashed line will appear on the tracing.

When 10 seconds of valid ECG data have been acquired by the device, the message "ACQUISITION COMPLETE" will be displayed and the unit will proceed to the transmission screen if it is configured to transmit after 12-lead analysis.

## 12-LEAD ECG DATA TRANSMISSION

The **M Series** unit can be configured to transmit 12-lead ECG data records to a fax machine or a Catalyst MUSE information system. See Appendix B for specific information about the Catalyst MUSE system and prerequisites for its use.

In order to fax using the 2x6 format, set the 12 Lead Fax Format configuration to "2x6," and the Auto Transmit After 12 Lead Analysis configuration to "Yes." Fax immediately after acquisition. The 2x6 fax image is not stored in the patient records. Patient data can, however, be reproduced in 4x3 format at a later time.

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**CAUTION**

Transmission of 12-lead ECG data via cellular phones can be less reliable than transmission via landline connections. A strong signal and stationary transmission will improve the transmission's success rate. Follow the directions provided with your cellular phone.

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If the **M Series** unit has been configured to automatically transmit 12-lead ECG data records to a fax machine or Catalyst MUSE system following completion of the acquisition phase, the following data transmission screen will be displayed.

| Phone #1 | | | | |
|---|---|---|---|---|
| Phone #2 | | | | |
| Phone #3 | | | | |
| Phone #4 | | | | |
| Prev Phone# | Next Phone# | Dial Phone# | Manual Dial | Cancel Xmit |

Pressing the **Prev Phone#** and **Next Phone#** softkeys will scroll the highlight up and down through the preconfigured phone destinations

Pressing the **Dial Phone#** softkey will dial the highlighted phone destination and begin the transmission process.

Pressing the **Manual Dial** softkey will display the following screen for entering the phone number:

| Prev Digit | Inc Digit | Dec Digit | Next Digit | Dial # or Return |
|---|---|---|---|---|

Pressing the **Prev Digit** softkey moves the highlight left to the previously entered digit.

Pressing the **Inc Digit** or **Dec Digit** softkey increments or decrements the selected digit.

Pressing the **Next Digit** softkey moves the highlight right to the next digit to be entered.

If a minimum of one (1) digit has been entered, pressing the **Dial Phone# or Return** softkey will dial the entered phone number and display the following screen:

| Abort | | | Alarms | |
|---|---|---|---|---|

Standard modem call progress status messages will follow as the various phases of the transmission progress.

If you are transmitting to a fax machine, the following messages display in sequence: "FAX PREPARING," "FAX DIALING," "FAX SENDING," "FAX DONE".

If you are transmitting to a Catalyst MUSE system, the following messages display in sequence: "MUSE DIALING," "MUSE SENDING," "MUSE DONE."

Pressing the **Abort** softkey will abort the transmission process. Turning the Selector Switch to another mode of operation (Defibrillation or Pacing) will also automatically abort the transmission.

When the transmission is complete, an error has occurred or the **Abort** softkey is pressed, the Retry screen will be displayed:

| Retry | | | Alarms | Return |
|---|---|---|---|---|

Pressing **Retry** will display the Transmission screen, so that transmission can be performed again. Pressing **Return** will display the main 12-lead screen. If 30 seconds elapse and a

softkey is not pressed, the main 12-lead screen will be displayed.

## Fault Conditions

### Transmission Error

In the event of a failure to transmit the ECG record, the operator will be notified and the **M Series** will continue to retry the transmission until the operator aborts the transmission or the transmission is successful. See "Troubleshooting" for possible transmission error messages and corrective actions.

### Check Recorder

If an out of paper condition or a paper jam condition occurs during printout of the 12-lead report, the operator will be notified but data transmission will continue. The operator can retrieve the 12-lead report by printing a Summary Report after the error condition is cleared.

## Settings Softkey

Pressing the **Settings** softkey from the 12-lead Monitor screen allows the user to change ECG Filter, Lead Group settings or Dial Type for 12-lead monitoring. ECG Filter and Lead Group setting defaults can be programmed via the Configuration mode of the **M Series**. (See the **M Series Configuration Guide, P/N 9650-0201-01,** for more information.)

| | | | | |
|---|---|---|---|---|
| | Filter | | | |
| | Lead Grp | | | |
| | Dial Type | | | |
| | Settings | Enter | | Return |

Once the settings screen is displayed, pressing the **Settings** softkey will scroll the highlighted area among the different available selections. Pressing **Enter** selects the setting that is highlighted. The **Return** softkey allows the user to return to the 12-lead Monitor screen.

AED units in Semi-Automatic monitor mode do not display "Filter" or "Lead Grp." Only "Dial Type" displays.

**Filter Setting**

Selecting the "Filter" setting allows the user to select among the following three filter / print format settings for 12-lead monitoring ONLY :

**0.05 – 150 4x3 channel printout (0.05 – 150Hz 4x3) :** When programmed to this setting, all 4x3 12-lead ECG reports will print with a 0.05 to 150 Hz bandwidth.

**0.05 – 150 Continuous printout (0.05 – 150Hz Cont.) :** When programmed to this setting, pressing and holding the **Recorder** button will print a continuous ECG strip using full diagnostic bandwidth until the **Recorder** button is released.   (This is an alternative to producing a 4x3 12-lead report in this fashion.  A 4x3 12-lead can still be printed using the **Acquire** softkey.)

**Note:** Use a diagnostic bandwidth of 0.05 to 150 Hz for diagnostic ECGs. ZOLL suggests using a 0.05 to 40 Hz setting in environments prone to noise.

**0.05 – 40 4x3 channel printout (0.05 – 40Hz 4x3)** : When programmed to this setting, all 4x3 12-Lead ECG reports will print with a 0.05 to 40 Hz bandwidth. This setting can be used to reduce excessive muscle or other artifact. This setting does

not alter the bandwidth of ECG data passed to the 12SL program. It only affects the printed waveforms.

Select the filter to be used by pressing the **Filter** softkey. The highlight area will scroll among the different filter choices. Press the **Enter** softkey to save the highlighted filter and return to the 12 Lead Monitor submenu.

**NOTE:** When the **M Series** is turned off for more than 10 seconds, all settings are restored to their original default settings.



### Lead Group Setting

The **M Series** 12-Lead Option allows any three ECG lead signals to be simultaneously printed on the strip chart recorder when using a 12-lead cable. When the **Standard** lead grouping is selected, leads I, II and III are printed together, leads aVR, aVL, and aVF are printed together, leads V1, V2, and V3 are printed together and leads V4, V5, and V6 are printed together. When either **Custom 1** or **Custom 2** lead grouping is selected, the three (3) leads printed on the recorder will be those previously programmed for the custom group via the Configuration mode of the **M Series** device.   (See the **M Series Configuration Guide, P/N 9650-0201-01,** for more information.)

### Standard

When programmed to this setting, 3-lead ECG recordings will be grouped as follows:

- leads I, II, and III
- leads aVR, aVL, and aVF
- leads V1, V2, and V3
- leads V4, V5, and V6.

The lead group that prints on the recorder in this mode will be the group containing the lead selected for display on the **M Series** screen. For example, if Lead II is displayed, leads I, II and III will be printed; if lead V3 is displayed, leads V1, V2, and V3 will be printed.

**NOTE:** When the **M Series** is turned off for more than 10 seconds, all settings are restored to their original default values.

### Custom

When the lead group is configured to either **Custom 1** or **Custom 2**, 3-lead ECG recordings will include the leads preconfigured for that custom group.

Pressing the **Lead Grp** softkey will scroll the highlight among the different selections allowing the user to select the appropriate Lead Group for three channel printing.

Press the **Enter** softkey to save the highlighted Lead Group and return to the 12 Lead Monitor menu.



### Dial Type Setting

Selecting the **Dial Type** setting allows the user to select either Tone or Pulse dialing.



Pressing the **Dial Typ** softkey toggles the highlight between both types of dialing modes. Press the **Enter** softkey to save the highlighted dial mode and return to the 12 Lead Monitor menu. Press the **Return** softkey to return to the 12 Lead Monitor menu without saving the highlighted dial mode.

## PT Info Softkey

Press the **PT INFO** softkey to access the patient demographic information.



Pressing the **PT INFO** softkey allows the user to select from the following softkeys:  **ID#**, **Age**, **Gender**, **Patient Records** or **Return**.

**Note:** If no information has been entered, the default age of "60" will be displayed above the **Age** softkey and the default gender of "Male" will be displayed above the **Gender** softkey. The 12SL algorithm processes ECG data based on age. All patients age 41 and older are handled in the same manner by the algorithm.

If a patient is under 41 years of age, you must **enter the patient's age.**  This is especially important because the 12SL algorithm contains age-specific criteria.  For patients 15 years of age or younger, the 12SL algorithm performs a pediatric analysis**.**

## Patient Identification Number (ID#)

Pressing the **ID #** softkey causes the "Name and ID#" screen to appear. "Name" is entered by pressing the **Prev Digit** and **Next Digit** softkeys to select the digit then pressing the **Inc Digit** and **Dec Digit** softkeys to select the value of the digit. When "Name" has been entered, press the **Enter Name** softkey. The highlight will automatically advance to the "Patient ID#" line. The Patient ID# is entered exactly the same way as above. When the ID# has been entered, press the **Enter ID and Return** softkey to return to the Patient Information Menu and store the name and ID number. If no patient ID # is entered the M Series automatically generates a 12 digit patient ID# based on the year/date/time (200002151320) of the first 12-lead acquisition.

| ID# | Age | Gender | Patient Records | Return |
|-----|-----|--------|-----------------|--------|

Whenever possible, enter a patient identification number (ID) before transmitting 12-lead ECG data to a Catalyst MUSE system. If the data does not have a unique ID number, the medical facility must search through all of its unidentified records to find the patient's information.

## Patient Age

Pressing the **Age** softkey causes the number displayed above the **Age** softkey to be highlighted. Press the **Dec Age** or **Inc Age** softkey to change the patient's age. Press the **Enter** softkey to save the highlighted age and return to the Patient Information screen. Press the **Return** softkey to return to the Patient Information screen without saving the highlighted age.

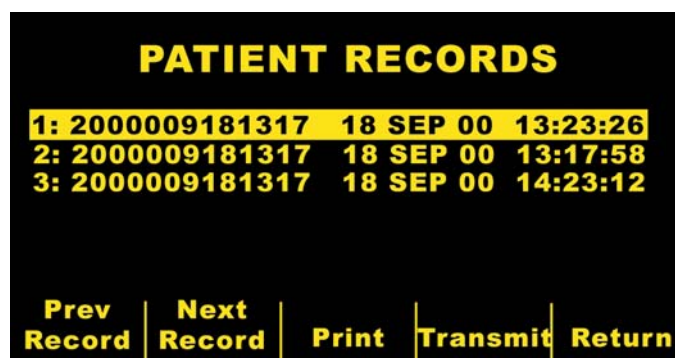| 60 | | | |
|----|----|----|----|
| Inc Age | Dec Age | Enter | Return |
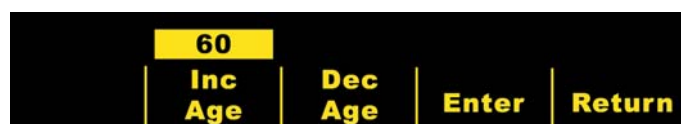
## Patient Gender

Pressing the **Gender** softkey toggles the highlight between both genders displayed above the **Gender** softkey. Press the **Enter** softkey to save the highlighted gender and return to the Patient Information screen. Press the **Return** softkey to return to the Patient Information screen without saving the highlighted gender.

| | Female | | |
|----|--------|----|----|
| | Male | | |
| | Gender | Enter | Return |

## Patient Records

Pressing the **Patient Records** softkey causes the Patient Records screen to appear. This screen is used to transmit or print specific 12-lead ECG records denoted by Patient ID #, date, and time. (Patient Records are stored in Summary memory. The user may wish to set Summary Report Restart Delay to 1.5 days in order to extend the storage time for 12-lead Patient Records. See the **M Series Configuration Guide**, **P/N 9650-0201-01**, for instructions on how to implement this feature.)

**PATIENT RECORDS**

| 1: 2000009181317 | 18 SEP 00 | 13:23:26 |
|------------------|-----------|----------|
| 2: 2000009181317 | 18 SEP 00 | 13:17:58 |
| 3: 2000009181317 | 18 SEP 00 | 14:23:12 |

| Prev Record | Next Record | Print | Transmit | Return |
|-------------|-------------|-------|----------|--------|

Pressing the **Prev Record** and **Next Record** softkeys will scroll the highlight up and down through the list of stored 12-lead records.

Pressing the **Print** softkey will print the selected 12-lead patient record on the strip chart. The format is the same as that stored in summary memory.

Pressing the **Transmit** softkey will transmit the selected 12-lead patient record. The Transmission Setup screen will appear as described in the Data Transmission section of this manual.

Pressing the **Return** softkey exits the Patient Records screen and displays the 12 Lead menu.

# 12-Lead Reports

Immediately after acquisition, the 12-lead data prints in the following order:

1. 12-Lead ECG waveforms

2. Patient information

3. ECG analysis using the GE Medical Systems Information Technologies 12SL Analysis Program (if configured)

4. Measurements matrix  (if configured)

See the figures below for a view of numbers 1, 2, and 4 above.

Optionally, the user can configure the unit to print median complexes in a 4x3 format or standard data in a 2x6 format for faxes. (Refer to the **M Series Configuration Guide, P/N 9650-0201-01,** for more details.)

## 12-Lead ECG Waveforms

| CAUTION |
|---|
| The 12SL analysis results can be affected by poor ECG data quality.  If poor data quality is flagged by the system, the interpretation statements will be preceded by the statement, "Poor data quality, interpretation may be adversely affected." If this message prints, the analysis results may be invalid. Check for "LEADS OFF" condition or other sources of noise, correct the condition, and re-acquire.  The ECG waveform should always be reviewed by a physician to confirm any automatic interpretation. |

**4x3 Format**

By default, the 4x3 format prints 10 seconds of 12-lead ECG data in four staggered 2.5 second segments. Each 2.5 second segment displays the ECG reading for one set of three leads (see figure). The report can be configured for either standard or Cabrera print formats. 1 mV calibration pulses are printed at the beginning of the report for each data channel.  You can also configure the M Series unit to print 5, 7.5, or 10 seconds of ECG data for each set of leads.  If you specify a setting of 5, 7.5, or 10 seconds, the M Series unit prints data for the same time period (5, 7.5, or 10 seconds) for each set of ECG leads; the M Series unit does not present the ECG data for the 5, 7.5, or 10 second periods in the staggered time format that it uses for the 2.5 second setting (this option applies only to real time 4x3 printouts, and does not apply to reports or to the data stored to the data card).

For information on how to change this default setting, see the **M Series Configuration Guide**, **P/N 9650-0201-01**.
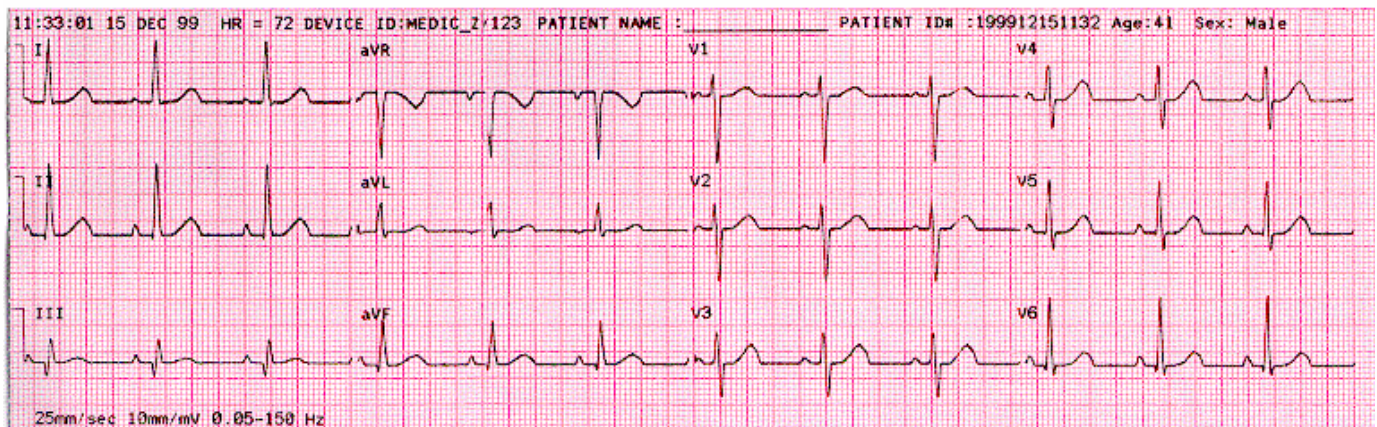
Standard 12-lead printout is always in 4x3 format unless configured differently.

**1st 2.5 sec ECG data**　　**2nd 2.5 sec ECG data**　　**3rd 2.5 sec ECG data**　　**4th 2.5 sec ECG data**

## 4x3 Median Complexes

This format prints a single median beat for each of the twelve (12) leads. The median beat is computed by the 12SL algorithm and is denoted by a squiggle at the end of each median lead. The report can be configured for either standard or Cabrera print formats. 1 mV calibration pulses are printed at the beginning of the report for each data channel.
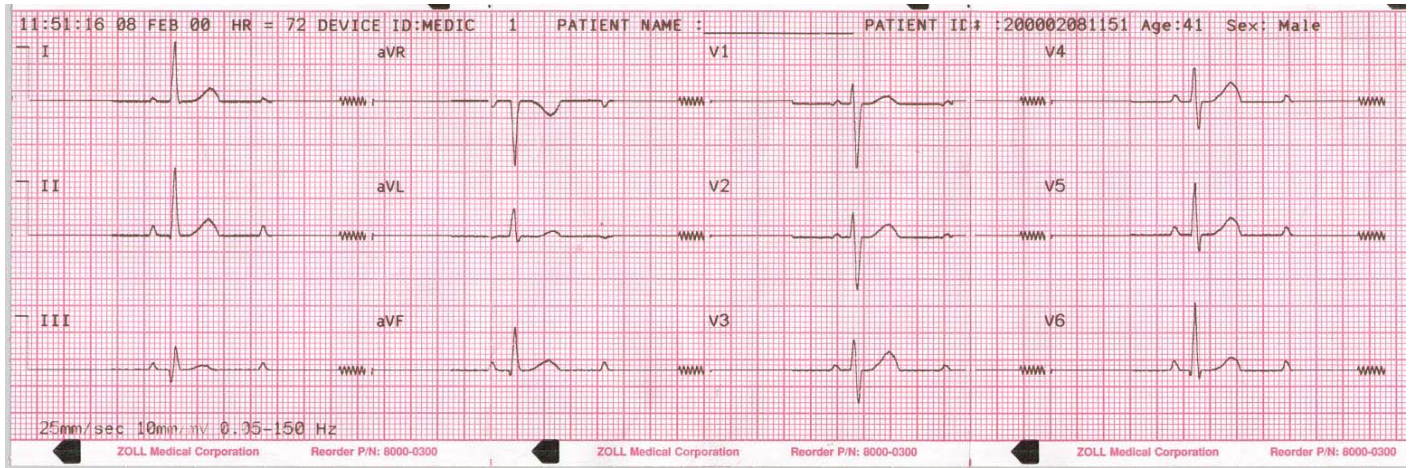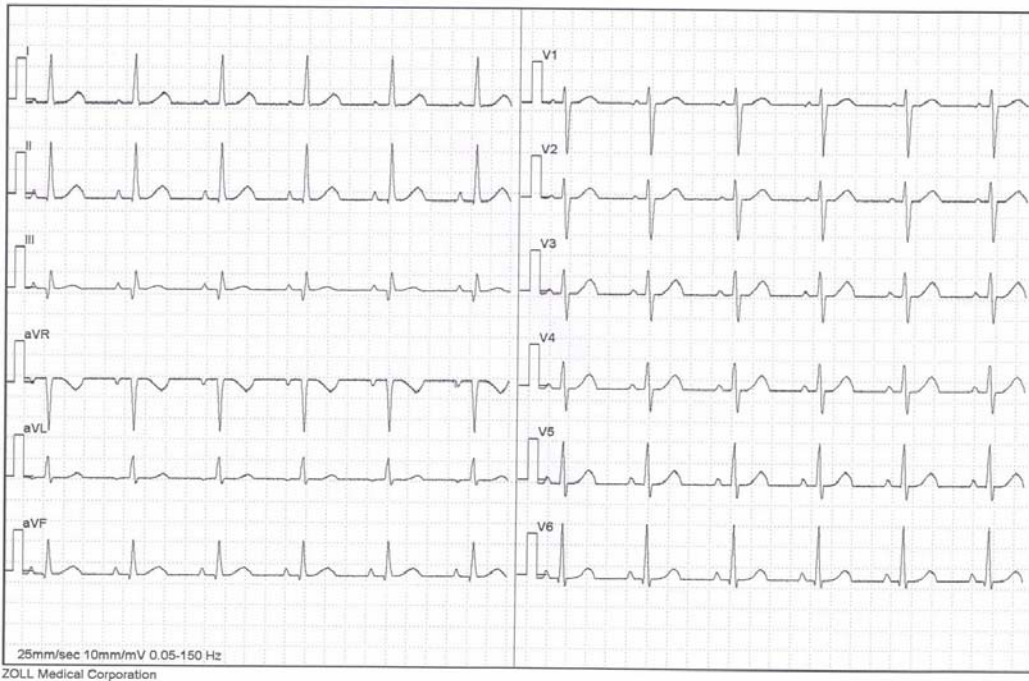


## 2x6 Format (Fax Report Only)

The "**2x6 Format, 1 Page**", prints all 12-lead ECG data recorded during the first 5 second interval. The 2x6 format inhibits printing of the 12SL analysis and the lead II rhythm strip normally printed on the fax page. The strip chart always prints in the 4x3 format.

Fax the 2x6 format immediately after acquisition. The 2x6 fax image is not stored in the patient records. Patient data can, however, be reproduced in 4x3 format at a later time.

## Patient Information

DEVICE ID: MEDIC_1

RECORDED: 11:33:01   15 DEC 99

PATIENT NAME : JOE SMITH

PATIENT ID: 199912150932

PATIENT AGE: 41

PATIENT SEX: Male

Vent.  Rate :          72

PR interval          146 ms

QRS Duration:        84 ms

QT/QTc        374 / 409 ms

P-R-T axes     64  39   48

Normal sinus rhythm

Normal ECG

*** Unconfirmed ***

## Measurements Matrix

The unit can be configured to print out a measurements matrix, which consists of measurements for each segment of each lead. To print the measurements matrix at the end of an analysis, the user must change the default setting in the **M Series** device (see the **M Series Configuration Guide**, **P/N 9650-0201-01**, for more details).

|      | PA   | PPA | QA   | QD | RA   | RD | SA   | SD | RPA | RPD | SPA | STJ | STM | STE | TA   | TPA |
|------|------|-----|------|----|------|----|------|----|-----|-----|-----|-----|-----|-----|------|-----|
| V1   | -14  | 78  | 0    | 0  | 332  | 26 | 1393 | 58 | 0   | 0   | 0   | -59 | -49 | 0   | 97   | 0   |
| V2   | 73   | 0   | 0    | 0  | 429  | 32 | 091  | 52 | 0   | 0   | 0   | -25 | -15 | 39  | 224  | 0   |
| V3   | 102  | 0   | 0    | 0  | 566  | 44 | 329  | 40 | 0   | 0   | 0   | -10 | 14  | 63  | 356  | 0   |
| V4   | 122  | 0   | 0    | 0  | 620  | 48 | 532  | 36 | 0   | 0   | 0   | -35 | -15 | 39  | 356  | 0   |
| V5   | 141  | 0   | 0    | 0  | 991  | 57 | 292  | 27 | 0   | 0   | 0   | 9   | 29  | 58  | 341  | 0   |
| V6   | 175  | 0   | 92   | 16 | 1284 | 49 | 166  | 19 | 0   | 0   | 0   | -25 | 0   | 9   | 249  | 0   |
| I    | 78   | 0   | 0    | 0  | 1132 | 65 | 63   | 19 | 0   | 0   | 0   | -35 | -35 | -10 | 253  | 0   |
| aVL  | 19   | -34 | 0    | 0  | 507  | 50 | 136  | 34 | 0   | 0   | 0   | -25 | -25 | -30 | 97   | 0   |
| II   | 175  | 0   | 68   | 10 | 1337 | 74 | 0    | 0  | 0   | 0   | 0   | -20 | -20 | 39  | 322  | 0   |
| aVF  | 146  | 0   | 102  | 17 | 830  | 67 | 0    | 0  | 0   | 0   | 0   | 0   | 0   | 43  | 200  | 0   |
| III  | 117  | 0   | 229  | 32 | 439  | 52 | 0    | 0  | 0   | 0   | 0   | 14  | 14  | 48  | 107  | 0   |
| aVR  | -126 | 0   | 1210 | 84 | 0    | 0  | 0    | 0  | 0   | 0   | 0   | 24  | 24  | -15 | -288 | 0   |

## 12SL Wave Measurement

After the P, QRS, and T complexes have been demarcated, the waves for each complex are identified. This is done separately for each lead. The program finds the points at which the signal crosses the baseline within each complex. If the crossing points define a wave that has an area greater than or equal to 160 μV/ms, the wave is considered to be significant. If the area is less than this value, the program considers the wave to be insignificant, and it will not label it as a separate wave. The measurement matrix contains the amplitudes (with respect to QRS onset) and durations of all of these individual waves.
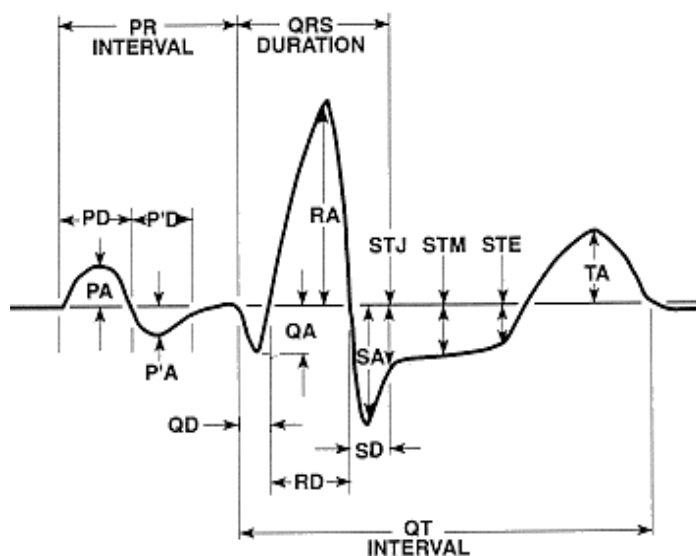


## Reviewing an ECG

**WARNING**

All computerized ECG analysis results must be reviewed by a physician before they are used to determine patient treatment.

ECG data can be viewed in three different ways:

1. **ECG Strip:** Displays a 12-lead strip of 10 seconds of ECG snippettes, in four staggered 2.5 second segments. For more information, see "4x3 Format" in the "12-lead Summary Reports" section of this insert.

2. **Interpretation:** Displays the results of interpretation of the ECG recording by the 12SL program.

3. **Measurements:** Measurements are displayed based on all 12-leads.

The global measurements include heart rate, PR Interval, QRS duration, QT & QTc, P axis, QRS axis, and T axis.

**Heart Rate:** frequency in beats per minute. Normal range is 60-100.

**PR Interval:** time between beginning of P wave and beginning of QRS complex. Sometimes referred to as PQ duration. Smaller values indicate premature excitation of the ventriculars, larger values indicate conduction defects in the atrioventricular (AV) node.

**QRS Duration:** duration of the QRS complex in milliseconds. Larger values indicate ventricular conduction defects.

**QT, QTc Duration:** time in milliseconds from beginning of QRS complex to end of T wave. The QTc value is QT corrected for heart rate to estimate the value it would have been if the heart rate were 60 bpm. Abnormal values can be due to electrolyte imbalances or drugs: short QT due to hyperkalaemia; long QT due to hypocalcemia or quinidine-like drugs (procainamide, amiodarone).

**P-axis:** axis of P wave in degrees.

**QRS axis:** axis of the QRS complex. Smaller than -30 is called left axis deviation, larger than 90 is right axis deviation. Deviations can be due to conduction blocks or hypertrophy.

**T-axis**: axis of the T-wave.

Following the global measurements is a table of lead-specific measurements for the standard 12-leads.

Next are amplitudes of individual waves and segments:

| | |
|---|---|
| **PA, PPA:** | minimum and maximum values of P wave |
| **QA, RA, SA:** | absolute amplitude of the indicated wave |
| **STJ:** | ST level at J-point |
| **STM, STE:** | ST level at the middle and end point of the S wave. |
| **TA, TPA:** | minimum and maximum values of T wave. |

All amplitudes are in μV (microvolts) or mm (at 10mm/mV) depending on the setup. Next are durations of individual waves and segments:

| | |
|---|---|
| **QD, RD, SD:** | duration of the indicated wave in ms. |
| **RPA, RPD, SPA:** | These measurements reflect the amplitude (RPA & SPA) and duration (RPD) of secondary R and S waves that may appear with RSR patterns such as right or left bundle branch block. |

**For interpretation of these results refer to the 12SL ECG Analysis Program Physicians Guide (ZOLL P/N 3001-0203).**

# Daily Operational Verification

1. Connect the V-lead cable to the 12-lead cable.
2. Connect the lead wires of the 12-lead cable and V-leads to the patient or 12-lead simulator. If connecting to a patient place ECG electrodes as indicated in the **Electrode Placement Section**.
3. Connect the ZOLL 12-lead cable to the connector located on the rear of the **M Series**.
4. Turn the Selector Switch of the **M Series** to Monitor.
5. Select a normal sinus rhythm on the Simulator.
6. Cycle through each of the 12 leads by pressing the **LEAD** button.
7. Verify that good quality, artifact-free ECG signals are displayed and stabilized within 10 seconds on your **M Series**.
8. Verify the ECG LEAD OFF message is NOT displayed on the screen.
9. Verify the LOW BATTERY message is NOT displayed on the screen.
10. Verify the filter setting is set for 0.05 – 150 Hz (4x3).
11. Press and hold the **RECORDER** button for 3 seconds.
12. Verify appropriate ECG signals are printed. See **12-lead Summary Reports Section** for reference.
13. Verify accuracy of time and date printed on the strip.
14. Visually inspect ECG Cable snaps for corrosion, particularly on the retaining wire inside the snap.

# Troubleshooting

The troubleshooting guide is intended to help you identify and correct problems that arise during operation. If trouble persists after consulting this guide, contact the ZOLL Technical Service Department for problems relating to the **M Series** unit or GE Medical Systems Information for problems relating to the Catalyst MUSE system.

ZOLL Technical Service Department
(USA)  Phone: (800) 348-9011
(UK)    Phone: +44-192-584-6400
(Others)  Contact your local ZOLL distributor

GE Customer Support
Phone: (800) 531-5613
Fax:      (414) 362-3200
Outside of USA/Canada:
Phone (561) 575-5060  Extension 4220

GE Technical Support
Phone: (800) 558-7044

| Symptom | Recommended Action |
|---|---|
| 1. The ECG baseline does not stabilize or the ECG is noisy, or the following message is displayed: "NOISY ECG". | 1. Verify the electrodes are connected properly to the patient. Reposition the electrodes and/or lead wires to prevent the electrodes from pulling away from the patient.<br>2. Verify the gel of the electrode is <u>not</u> dry. Check expiration date on the electrode package.<br>3. Use Silver/Silver Chloride electrodes.<br>4. Verify patient cable is connected properly and held motionless. Verify that the ECG snaps and connectors are clean.<br>5. Make sure that the patient is motionless. Support patient's limbs, if necessary.<br>6. Stop vehicle while acquiring the 12-lead ECG.<br>7. Verify correct filter (50 or 60 Hz) is selected in Configuration menu.<br>8. Inspect ECG cable. Replace if damaged.<br>9. Change ECG Filter setting to 0.05-40 Hz 4x3 and retry acquisition. |
| 2. "ECG LEAD OFF" or "VX LEAD OFF" | 1. Confirm ECG electrode and cable connections.<br>2. Prepare skin and replace electrodes.<br>3. Check ECG cable continuity and replace if cable damage is suspect.<br>4. ECG signal may be temporarily out of range due to recent defibrillator discharge. |

| | |
|---|---|
| 3. Unsuccessful transmission to fax (e.g., transmission stops before completion, signal disappears, etc.) | 1. Check modem connection (card and extension cable) to **M Series**.<br><br>2. Check modem connection to phone jack or cellular phone.<br><br>3. Power cycle cellular phone.<br><br>4. Make sure receiving fax is turned on.<br><br>5. Check the phone number and attempt to send again.<br><br>6. Check the telephone line (landline).<br><br>If you are using a cellular phone, be aware that cell signals vary depending on the carrier and area. If you continue to experience problems, switch to a land line. |
| 4. Unsuccessful transmission to MUSE | 1. Check modem connection (card and extension cable) to **M Series**.<br><br>2. Check modem connection to phone jack or cellular phone.<br><br>3. Power cycle cellular phone.<br><br>4. Verify with hospital system administrator that the Catalyst MUSE system's modem is operational.<br><br>5. Check the phone number and attempt to send again.<br><br>If multiple Catalyst MUSE phone numbers are configured, transmit to an alternate number.<br><br>6. Check the telephone line (landline).<br><br>If you are using a cellular phone, be aware that cell signals vary depending on the carrier and area. If you continue to experience problems, switch to a land line.<br><br>7. Check the **M Series** configuration for valid Catalyst MUSE site and location identifiers. |
| 5. "FAX BUSY" or "MUSE BUSY" message is displayed. | Receiving phone line is being used. The **M Series** automatically re-transmits until the transmission is successful or the **M Series** operator presses the **Abort** softkey.<br><br>If transmitting to a Catalyst MUSE system and multiple Catalyst MUSE phone numbers are configured, press the **Abort** softkey and transmit to an alternate number. |
| 6. "FAX ERROR" or "MUSE ERROR" message is displayed. | A dialing problem other than a busy line, no carrier, or no connection occurred. If transmitting to a Catalyst MUSE system, a problem with the receiving system that is not explained by another Catalyst MUSE error message occurred.<br><br>The **M Series** automatically re-transmits until the transmission is successful or the **M Series** operator presses the **Abort** softkey.<br><br>If transmitting to a Catalyst MUSE system and multiple Catalyst MUSE phone numbers are configured, press the **Abort** softkey and transmit to an alternate number. |
| 7. "FAX HANGUP" or "MUSE HANGUP" message is displayed. | Receiving phone is not receiving transmission. The **M Series** automatically re-transmits until the transmission is successful or the **M Series** operator presses the **Abort** softkey.<br><br>If transmitting to a Catalyst MUSE system and multiple Catalyst MUSE phone numbers are configured, press the **Abort** softkey and transmit to an alternate number. |

| 8. "FAX INTERRUPTED" or "MUSE INTERRUPTED" message is displayed. | 1. Power cycle **M Series** unit and retry transmission.<br><br>2. Contact ZOLL Technical Service Department. |
|---|---|
| 9. "FAX NO CARRIER" or "MUSE NO CARRIER" message is displayed. | Receiving phone line is not picking up or the sending modem is experiencing problems. The **M Series** automatically re-transmits until the transmission is successful or the **M Series** operator presses the **Abort** softkey.<br><br>If retransmissions fail:<br><br>1. Check modem connection (card and extension cable) to **M Series**.<br><br>2. Power cycle cellular phone.<br><br>3. If transmitting to a Catalyst MUSE system and multiple Catalyst MUSE phone numbers are configured, press the **Abort** softkey and transmit to an alternate number.<br><br>4. If transmitting to a Catalyst MUSE system, check that the Catalyst MUSE system's phone numbers are set up correctly. See the ZOLL **M Series Configuration Guide, P/N 9650-0201-01,** for further information. |
| 10. "FAX NO DIAL TONE" or "MUSE NO DIAL TONE" message is displayed. | 1. Check modem connection (card and extension cable) to **M Series.**<br><br>2. Check modem connection to phone jack or cellular phone.<br><br>3. Power cycle cellular phone. |
| 11. "MODEM REQUIRED" message is displayed. | No PCMCIA modem card present. Insert PCMCIA modem card in upper slot and repeat transmission. |
| 12. "MUSE CANCEL" message is displayed. | **The M Series** operator pressed the **Abort** softkey or turned the selector switch to Defib or Pacer. |
| 13. "MUSE DATA NOT VALID" message is displayed. | An overriding activity, such as an alarm situation, preempted data in the process of being saved to the **M Series** unit. The data is incomplete or corrupted.<br><br>Re-acquire 12-lead data and re-transmit. |

# APPENDIX A

# MODEM AND PHONE SETUP

The **M Series** with 12-Lead option may include a modem for transmitting 12-lead ECG information to remote locations via landline or cellular phone. This section describes how to connect your **M Series** for phone transmission.

### Modem

- When included, the **M Series** with 12-Lead option ships with a cellular-ready PC card modem installed in the upper PCMCIA slot (domestic units only).

- The **M Series** with 12-Lead option is also available with an approved GSM card modem (obtained locally for international customers).
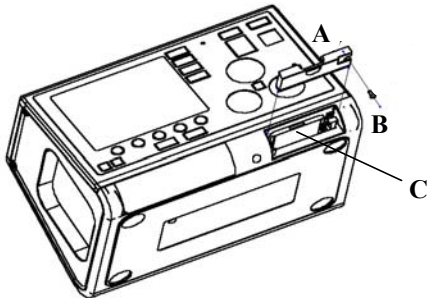
   *Note:  Only the upper PCMCIA slot supports modem communication.  DO NOT attempt to insert the modem into the lower slot.*

   *Note:  The **M Series** does not support all PCMCIA type modems. Contact ZOLL Technical Support before attempting to use modems other than those supplied with the unit.*

   *ZOLL Technical Support*
   *Phone: (800) 348-9011*

M Series with Modem



The modem can be removed for service or cleaning by removing screw B and sliding bezel A out of the PCMCIA slot.  The modem C is then removed by depressing the plunger to the right of the modem card until the modem is free to slide out.

### Cables

- Not all cell phones transmit ZOLL data reliably. See your local ZOLL Sales Representative for a list of ZOLL-approved cell phones.

- A landline phone cable comes with modem equipped **M Series** units.  This cable connects to the modem on one end and plugs into a standard RJ-11 phone jack on the other end.  The RJ-11 is compatible with POTS (Plain Old Telephone System) phone lines such as those found in most residential homes or used for fax machines.

- The modem in the **M Series** is compatible with certain AMPS (analog) or dual-mode cellular phones in the U.S.A., and with certain GSM cellular phones in Europe, depending on modem model.  Each model phone

requires a specific modem- to-cell phone interconnect cable.  Cables may be purchased through The Supply Net, Inc. in Valley Cottage, NY:

www.thesupplynet.com
Phone:         (800) 826-0279
Fax:            (914) 267-2420

International customers should contact their local ZOLL representatives for their local supplier of cellular phone cables and upgrade kits.

- For connection to a Motorola 3-Watt "**Bag Phone**" or vehicle-mounted phone, ZOLL recommends using the included landline cable  along with Motorola's Cellular Connection, Model S1936D. This  device is also known as a "dial tone generator" and is used to interface the RJ11 landline connector with the 3-Watt cellular phone. The Motorola Model S1936D along with support for vehicle-mounted phones is available through AirDesk, Inc. in Warminster, PA:

www.800airdesk.com
Phone: (800) 882-1288 M-F 8:30 AM – 5:30 PM EST        (800) 206-6108 M-F 5:30 PM – 8:00 PM EST
Fax:    (215) 734-8000

- The **M Series** cellular-ready PC card modem may be used with ZOLL's ruggedized cellular-ready modem extension cable.  This cable is available as part of the Xtreme Pack II or as a standalone item in the following configurations:
  - Xtreme Pack II with rear pouch and cellular ready modem extension cable.
  - Xtreme Pack II with rear and side pouches and cellular ready modem extension cable.
  - Cellular ready modem extension cable, standalone.
  - Cellular ready modem extension cable upgrade kit for existing Xtreme Pack II.

  For information on ordering these items, please contact your local ZOLL sales representative.

- To reduce wear on the connector, keep the phone cable plugged into the extension cable when the extension cable is in use. In this manner, the user would primarily disconnect from the phone at the phone end of the cable.

- When first connecting the phone cable to the modem or modem extension cable, note the orientation of the connectors for future reference.  The connectors are keyed and only mate in one orientation.

## Configuring Phone Numbers

- Please see the ZOLL **M Series Configuration Guide**, P/N 9650-0201-01, for instructions on how to program automatic-dial phone numbers into the **M Series** unit.

- Manual phone number entry is described in the Data Transmission section of this document.

## Configuring the Modem for Cellular Phones

The cellular-ready PC card modem comes pre-configured for landline and certain Nokia or  Motorola cellular phones.

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> **CAUTION**
>
> - Data transmission via cellular phones can be less reliable than transmission via landline connections. A strong signal and stationary transmission will improve the transmission's success rate. Follow the directions provided with your cellular phone.
>
> - Many hospitals prohibit the use of cellular phones on their premises. Please abide by local rules and regulations.

## TRANSMISSION SPECIFICATIONS

**Fax**
- Group 3 Facsimile
- FAX Software Interfaces
  Class 2, EIA-TR29.2
  Class 1

**Catalyst MUSE**
Catalyst MUSE revision 4B and higher

# Telephone Company Requirements

The following regulations apply to modems used within the United States and Canada.

## FCC Regulations

- The FCC has established rules that permit this device to be directly connected to the telephone network, using a standardized jack. Do not use this equipment on a party line or coin line.

- Malfunctioning equipment may cause damage to the telephone network. If this device is not functioning properly, disconnect it until the problem has been determined and the device has been repaired. Otherwise, the telephone company may disconnect service temporarily.

- The modem card is a non-serviceable/repairable item. It is the responsibility of the user to report the need for any service to the device to ZOLL Medical Corporation.

- If you encounter any problems with your telephone after installing any new device, disconnect it from the telephone line to see if the device is the source of the problem.

- The telephone company may make changes to its technical operations and procedures. If such changes affect the compatibility or use of this device, the telephone company is required to provide adequate notice of the changes.

## Phone Company Requests

If the telephone company requests information about the equipment connected to their lines, inform them of:

1. The telephone number to which the device is connected.

2. The ringer equivalence number (REN), which is found on the FCC sticker attached to the modem. The REN determines how many devices may be connected to the same telephone line. If too many devices are attached, they may not ring properly. In most areas, the sum of the ringer equivalence numbers of all devices connected to the same line should not exceed five.

3. The USOC telephone jack required (RJ11, RJ41, or RJ45).

4. The FCC registration number, which is found on the FCC sticker attached to the modem.

**Interference**

---

**WARNING**

Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

---

This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference, in which case the user will be required to correct the interference at his own expense. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Re-orient the receiving antenna.

- Relocate the receiving antenna and/or equipment away from the modem.

- Relocate the modem away from the receiving antenna and/or equipment.

- Plug the modem into a different outlet so that the modem and the receiving equipment are on different electrical circuits.

If none of these actions resolves the problem, consult your distributor or an experienced radio/television technician for additional suggestions.

### FCC Rules and Regulations - Part 68

This equipment complies with Part 68 of the FCC Rules. On the back of the modem card is a label that contains, among other information, the FCC Registration Number and Ringer Equivalency Number (REN) for this equipment. You must, upon request, provide this information to your telephone company.

The REN is useful to determine the quantity of devices you may connect to your telephone line and still have all those devices ring when your telephone number is called. In most but not all areas, the sum of the RENs of all devices connected to one line should not exceed five (5.0). To be certain of the number of devices you may connect to your line, as determined by the REN, you should contact your local telephone company to determine the maximum REN for your calling area.

If your telephone equipment causes harm to the telephone network, the telephone company may discontinue your service temporarily. If possible, they will notify you in advance. But if advance notice is not practical, you will be notified as soon as possible. You will be informed of your right to file a complaint with the FCC.

Your telephone company may make changes in its facilities, equipment, operations or procedures that could affect the proper functioning of your equipment. If they do, you will be notified in advance to give you an opportunity to maintain uninterrupted telephone service.

If you experience trouble with this telephone equipment, please contact ZOLL Medical Corporation, for information on obtaining service or repairs. The telephone company may ask that you disconnect this equipment from the network until the problem has been corrected or until you are sure that the equipment is NOT malfunctioning.

There are no user serviceable parts contained in this equipment.

This equipment may not be used on coin service provided by the telephone company. Connection to party lines is subject to state tariffs.

### Shielded Cables

The use of any cable other than the shielded type will allow your system to emit more radio frequency interference than the FCC limits, thereby increasing the likelihood of interference. Therefore, in order to comply with the FCC regulations, it is necessary that you use good quality shielded cables with your installation.

## Canadian Requirements

The Industry Canada, formerly the Canadian Department of Communications, label identifies certified equipment. This certification means that the equipment meets certain telecommunications network protective, operational, and safety requirements. The Department does not guarantee the equipment will operate to the user's satisfaction.

Before installing this equipment, users should ensure that their local telecommunications company permits connecting it to their facilities. The equipment also must be installed using an acceptable method of connection. In some cases, the company's inside wiring associated with single line, individual service may be extended by means of a certified connector assembly (telephone extension cord). The customer should be aware that compliance with the above conditions may not prevent degradation of service in some situations.

Repairs to certified equipment should be made by an authorized Canadian maintenance facility designated by the supplier. Any repairs or alterations made by the user to this equipment or equipment malfunctions may give the telecommunications company cause to request the user to disconnect the equipment.

Users should ensure, for their own protection, that the electrical ground connections of the power utility, telephone lines, and internal metallic water pipe system, if present, are connected together. This precaution may be particularly important in rural areas.

---

**CAUTION:**

Users should not attempt to make such connections themselves, but should contact electric inspection authorities or electricians, as appropriate.

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To prevent overloading, a Load Number (LN) has been assigned to each terminal device to denote the percentage of the total load to be connected to a telephone loop which is used by the device. The termination on a loop may consist of any combination of devices subject only to the requirement that the total number of devices not exceed one hundred.

# APPENDIX B

# 12-LEAD ECG DATA TRANSMISSION TO CATALYST™ MUSE® SYSTEM

The ZOLL **M Series** with 12-Lead and Catalyst™ MUSE® interface allows for direct transmission of 12-lead ECG records to a GE Medical Systems Catalyst MUSE system. The Catalyst MUSE system provides access to online patient ECG records and enables physicians to quickly view and compare prehospital or hospital 12-lead data. Catalyst MUSE is a trademark of GE Medical Systems.

**Prerequisites**
Not all cell phones transmit to the Catalyst MUSE system reliably. See your local ZOLL Sales Representative for a list of ZOLL-approved cell phones. Before you can transmit 12-lead data to a Catalyst MUSE system, you must contact the Catalyst MUSE system administrator at the medical facility where the system is located. The system administrator will then:

- Authorize transmission to the system
- Provide you with telephone numbers for accessing the system
- Provide you with site and location identifiers for the **M Series** unit
- Set up the **M Series** site and location identifiers on the Catalyst MUSE system
- Configure the Catalyst MUSE system to forward ECGs to physicians or devices such as carts or fax machines

Ask the person responsible for configuring the **M Series** unit to set up the telephone numbers and the MUSE site and location identifiers that the Catalyst MUSE system administrator provided. It is recommended that the **M Series** device identifier also be configured. For more information, see the following sections in the **M Series Configuration Guide, P/N 9650-0201-01**:

- Device Identifier
- Fax/Communication Phone Numbers
- MUSE Site and Location

When these activities are complete, you can begin transmitting 12-lead ECG data to the Catalyst MUSE system.

**Note:** Whenever possible, enter a patient identification number (ID) before transmitting 12-lead ECG data to a Catalyst MUSE system. If the data does not have a unique ID number, the medical facility must search through all of its unidentified records to find the patient's information. To set up a patient ID number, see the "Patient Identification Number" section in this insert.