12-Lead ECG Monitoring

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12-LEAD ECG MONITORING

General Information

 ECG leads are a defibrillation-protected Type CF patient connection.

Product Description

ZOLL E Series® with the 12-lead ECG Monitoring option provides simultaneous 12-lead ECG acquisition, storage, transmission, and optional ECG analysis using the GE Medical Systems Information Technologies 12SL™ Analysis Program.

The Catalyst™ MUSE® interface allows 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 and hospital 12-lead data.

Intended Use

The ZOLL E 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 E Series with 12-lead option. It does not contain information on how to read or interpret electrocardiograms (ECGs). It covers the following:

WARNINGS

- Before use, carefully read the *E Series Operator's Guide* and these operating instructions.
- Always ensure that the patient is kept motionless during 12-lead ECG signal acquisition and analyses. Use of the device to acquire ECG signals from moving or shaking patients may produce erroneous 12-lead interpretation results.
- The E 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.
- Remove ECG electrodes from their sealed package immediately prior to use. Using previously opened or out-of-date electrodes may degrade the ECG signal quality.
- 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; the circuitry in the instrument returns 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.
- When not in use, cover the patient cable's V-lead connector with the supplied plastic cap. 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 E Series unit or any of its accessories.
- Check the operation and integrity of the E 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.
- 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 stripchart 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. Carefully observe pacemaker patients. 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

Depending on local usage, ECG lead wires are marked with certain labels. Refer to the following table for labels and color codes for the different lead sets.

Location	AHA[1] Labels	IEC[2] 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

[1] American Heart Association
[2] International Electrotechnical Commission

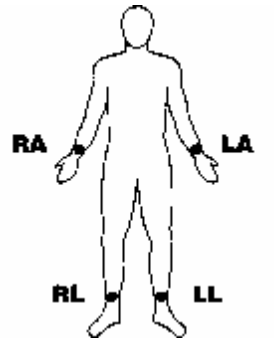
Proper skin preparation and use of proper electrodes are very important for good signal quality.

If necessary, prepare the patient's skin for electrode application by:

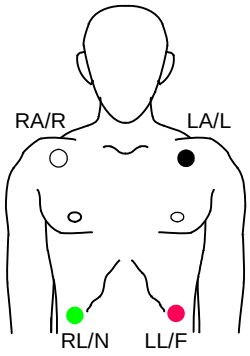
- Shaving or clipping excess hair at electrode site.
- Cleaning oily skin with an alcohol pad.
- Rubbing site briskly to dry.
- Avoiding placing electrodes over tendons and major muscle masses.

Place electrodes on the patient. All electrodes must be connected.

When acquiring 12-lead ECG from quiet supine patients, ZOLL Medical Corporation 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, place limb electrodes on patient's thorax for better results. (Refer to the following two diagrams for limb electrode placement).



AHA Placement



IEC and Alternate AHA Placement

Place the precordial electrodes across the chest in the following locations:

V1: Fourth intercostal space, at the patient's right sternal margin.

V2: Fourth intercostal space, at the patient's left sternal margin.

V3: Fifth rib, between leads V2 and V4.

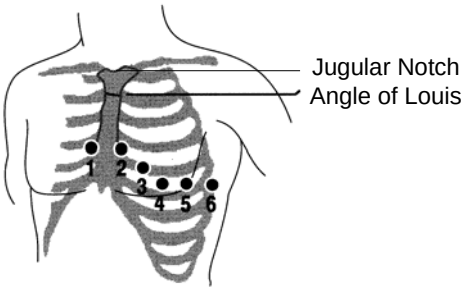
V4: Fifth intercostal space, on the patient's mid-clavicular line.

V5: Patient's left anterior axillary line, at the horizontal level of V4.

V6: Patient's 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 intercostal space on the patient's 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

The E Series unit begins pre-acquisition of 12-lead data when you attach the electrodes to the patient, as follows:

1. Attach electrodes to the patient lead wires.
2. Attach lead wires and electrodes to the patient, refer to "Electrode Placement" on page 3.
3. 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.)
4. Attach the 12-lead cable to the ECG connector at the back of the E Series product.

   Arrange the 12-lead cable such that it is neat and not dangling or looped, and assure that it is not pulling on individual electrodes.
5. Turn the selector switch to MONITOR mode.
6. If PADS or PADDLES are selected, select Lead I. (You must select leads to obtain a 12-lead printout.)
7. If the unit is configured to print 12-lead 4x3 reports, press the **RECORDER** button for 3 seconds to initiate 12-lead printout.

   The unit begins printout of the 12-lead report. This report consists of 10 seconds of 12-lead ECG data printed in four staggered 2.5 second segments.

Note: If the V-leads are not in use, pressing and holding the **RECORDER** button for 3 seconds, causes a 2 x 3 report to be printed. This report consists of 5 seconds of ECG data printed in two staggered 2.5 second segments (lead I, II and III, and lead aVR, aVL, and aVF).

To transmit the 12-lead report to a fax machine or Catalyst MUSE system, refer to "12-Lead ECG Data Transmission" on this page.

Physiological Monitoring

When the E Series device is turned to MONITOR, the physiological monitoring menu is displayed with the following softkeys: **Param**, **Wave 2**, **ID#**, **Alarms** and **12 Lead**.

If you enter 12-lead monitoring with two (2) waveforms displayed, both waveforms remain displayed on the screen during the 12-lead monitoring. To remove the second waveform prior to entering 12-lead monitor mode, press the **Wave 2** softkey.

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

12 Lead Softkey

When you press the **12 Lead** softkey, the following screen appears:

Acquire Softkey

WARNING

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

For the E Series to produce a formatted ECG recording and 12SL analysis, press the **Acquire** softkey. The message *ACQUIRING ECG* displays and the **Acquire** softkey changes to Halt.

Press the **Halt** softkey during acquisition to stop the data collection process. The monitor displays an *ACQUISITION HALTED* message and changes the leftmost softkey back to Acquire.

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

If one or more of the V-leads is not properly attached to the patient, an *ECG VX LEAD OFF* message is displayed on the screen ("VX" indicates the specific V-leads that are not attached to the patient).

If one or more of the limb leads is not properly attached to the patient, an *ECG LEAD OFF* message is displayed on the screen and a dashed line appears on the tracing.

When 10 seconds of valid ECG data have been acquired, the message *ACQUISITION COMPLETE* is displayed. The data is then analyzed, during which the message *ANALYZING 12 LEAD* is displayed. When the analysis is done, the message *ANALYSIS COMPLETE* is displayed and the unit proceeds to the transmission screen if it is configured to transmit after 12-lead analysis.

12-Lead ECG Data Transmission

The E Series unit can be configured to transmit 12-lead ECG records to a fax machine or a Catalyst MUSE information system. For information about the Catalyst MUSE system and prerequisites for its use, see "APPENDIX B: 12-Lead ECG Data Transmission to Catalyst MUSE System" on page 23.

In order to fax using the 2x6 format, set the 12 Lead Fax Format configuration option to 2x6, and the Auto Transmit After 12 Lead configuration option to Yes. Refer to the *E Series Configuration Guide* for instructions on setting these options.

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

CAUTION

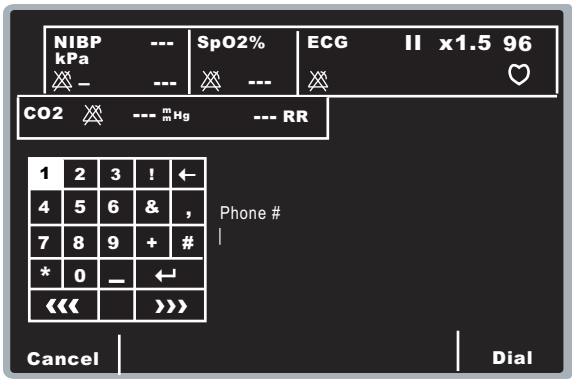
Transmission of 12-lead ECG data via cellular phones can be less reliable than transmission via landline connections. A strong signal and stationary transmission improves the transmission's success rate. Follow the directions provided with your cellular phone.

If the E 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 is displayed.

Press the **Prev Phone#** and **Next Phone#** softkeys to scroll the highlight up and down through the preconfigured phone/fax destinations.

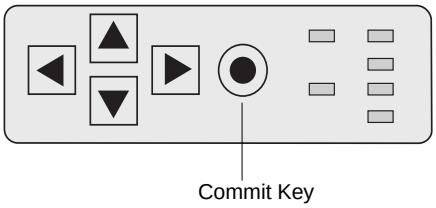
Then, press the **Dial Phone#** softkey to dial the highlighted phone/fax destination and begin the transmission process.

To manually dial a number, press the **Manual Dial** softkey to display the Manual Dial menu. Next, press the **Select Type** softkey to change data type (either fax or data), then press the **Enter** softkey to display the Manual Dial screen with keypad.

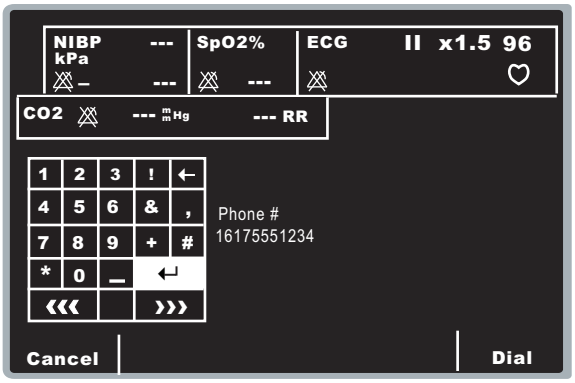


Use the scroll keys on top of the unit to select a number or character on the keypad, then press the **Commit** (⦿) key on top of the unit (see the next figure) to enter the digit in the Phone # field. Repeat for each additional digit (up to 20 characters).

Keypad on top, right side of unit.



When you have entered the phone number, select the **Enter** (↵) key from the keypad and press the **Commit** (⦿) key on top of the unit to initiate dialing, or press the **Dial** softkey.



Note: If at least one digit has been entered, pressing the **Dial** softkey or highlighting the **Enter** (↵)key on the keypad and pressing the **Commit** (⦿) key dials the entered phone number and displays the following screen:

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

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

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

If you need to abort the transmission, press the **Abort** softkey. Note that if you turn the selector switch to another mode of operation (DEFIB or PACER), the transmission is automatically aborted.

The Retry screen is displayed whenever one of these things occur:

- The transmission is complete.
- An error has occurred.
- The Abort softkey is pressed.

Pressing **Retry** displays the Transmission screen, so that transmission can be performed again. Pressing **Return** displays the main 12-lead screen. If 30 seconds elapse and a softkey is not pressed, the main 12-lead screen will be displayed.

Note the following fault conditions:

- Transmission Error

  In the event of a failure to transmit the ECG record, you are notified with a screen message and tones, and the E Series continues to retry the transmission until the operator aborts the transmission or the transmission is successful. See “Troubleshooting” on page 14 for possible transmission error messages and corrective actions.

- Check Recorder

  If the recorder runs out of paper or a paper jam occurs during printout of the 12-lead report, you are notified with a screen message and tones, and data transmission continues. The operator can retrieve the 12-lead report by printing a summary report after the error condition is cleared.

Settings Softkey

To change ECG Filter, Lead Group settings or Dial Type settings, press the **Settings** softkey from the 12-lead Monitor screen. (Note that you can change defaults for ECG Filter and Lead Group via the E Series Configuration mode; see the *E Series Configuration Guide* for more information.)

Once the settings screen is displayed, press the **Settings** softkey again to scroll through and highlight the different available selections. Press the **Enter** softkey to select the setting that is highlighted. You can return to the 12-lead Monitor screen by pressing the **Return** softkey.

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

Filter Setting

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

- 0.05 - 150 Hz frequency 4x3 channel printout:
  With this (0.05 - 150Hz 4x3) setting, all 4x3 12-lead ECG reports print with a 0.05 to 150 Hz bandwidth.
- 0.05 - 150 Hz frequency continuous printout:
  With this (0.05 - 150Hz Cont.) setting, pressing and holding the RECORDER button prints a continuous ECG strip using full diagnostic bandwidth until the RECORDER button is released.

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

- 0.05 - 40 4x3 channel printout (0.05 - 40Hz 4x3): With this setting, all 4x3 12-Lead ECG reports print with a 0.05 to 40 Hz bandwidth. Use this setting 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 you want to use by pressing the **Filter** softkey. The highlight area scrolls among the different filter choices. Press the **Enter** softkey to save the highlighted filter and return to the 12 Lead Monitor sub-menu.

Note: When the E Series is turned off for more than 10 seconds, all settings are restored to their default settings.

Lead Group Setting

The E Series 12-Lead option allows any three ECG lead signals to be simultaneously printed on the stripchart recorder when using a 12-lead cable. You can choose options Standard, Custom 1 or Custom 2, as follows:

- Standard

  When programmed to this setting, 3-lead ECG recordings are grouped and printed together 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 is the group containing the lead selected for display on the E Series screen. For example, if lead II is displayed, leads I, II and III are printed; if lead V3 is displayed, leads V1, V2, and V3 are printed.

Note: When the E Series is turned off for more than 10 seconds, all settings are restored to their default values.

- Custom

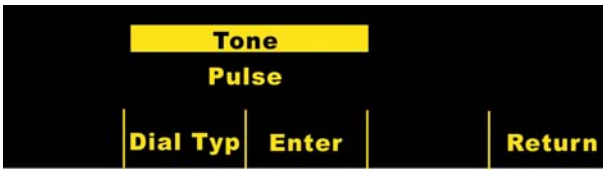
  When the lead group is configured to either Custom 1 or Custom 2, 3-lead ECG recordings include the leads preconfigured for that particular custom group. (See the *E Series Configuration Guide* for more information.)

Press the **Lead Grp** softkey to scroll through and highlight the different Lead Group selections 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 you to select either Tone or Pulse dialing.



Press the **Dial Type** softkey to toggle between both types of dialing modes. Press the **Enter** softkey to save the highlighted dial mode and return to the 12 Lead Monitor menu. If you want to return to the 12 Lead Monitor menu without saving the highlighted dial mode, press the **Return** softkey.

PT Info Softkey

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

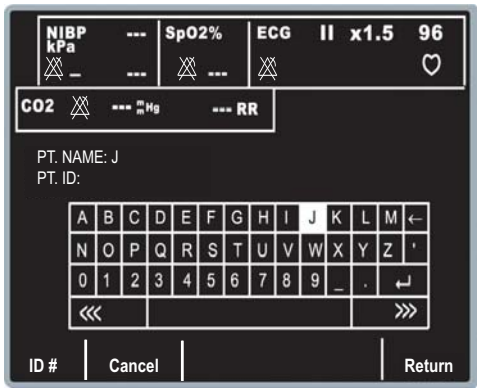
You can select from the following softkeys: **ID#**, **Age**, **Gender**, **Patient Record** or **Return**.

Note: If no information is entered, the default age of 60 is displayed above the **Age** softkey and the default gender of Male is 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#)

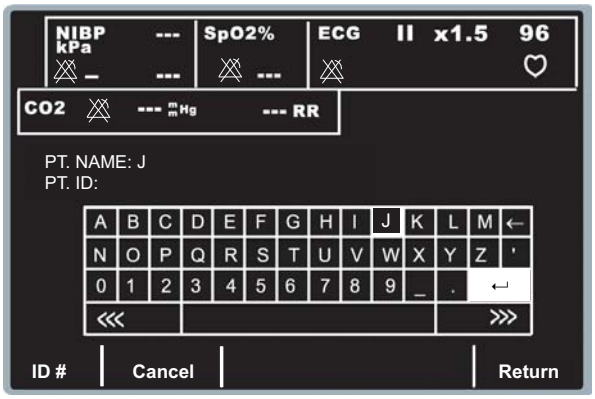
Press the **ID #** softkey to access the Name and ID# screen. The cursor goes directly to Patient Name field. If you don't want to enter a name, press the **ID #** softkey to move the cursor to the Patient ID field. Otherwise, use the scroll keys on top of the unit to select a character on the keypad, then press the **Commit** (⊙) key on top of the unit to enter the character in the Patient Name field.



Repeat for each additional character (up to 14) in the Patient Name field.

When you have entered the patient name, select the **Enter** (↵) key from the keypad and press the **Commit** (⊙) key on top of the unit (or you can press the

Return Softkey to save the information). The highlight automatically advances to the Patient ID# line.



The Patient ID# characters are entered exactly the same way as patient name characters above. When the ID# has been entered, select the **Enter** (↵) key from the keypad and press the **Commit** (⦿) key on top of the unit to store the name and ID number and return to the Patient Information menu (or you can press the **Return** Softkey to save the information).

If you do not want to enter a Patient ID#, use the scroll keys to select the **Enter** (↵) key from the keypad, and then press the **Commit** (⦿) key. If no patient ID # is entered, the E Series automatically generates a 12 digit patient ID# based on the year/date/time (200002151320) of the first 12-lead acquisition.

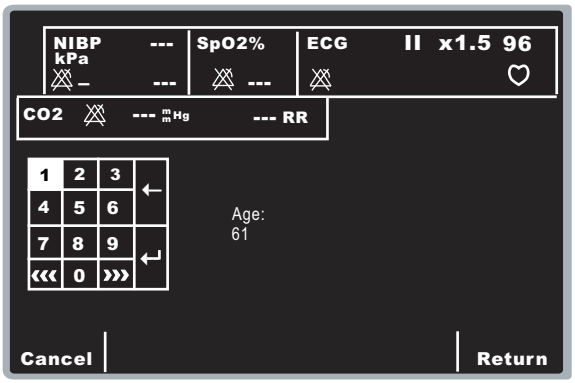
Use the **Cancel** softkey to exit this screen without saving the information.

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.

Patient Age

To set the patient age, press the **Age** softkey, to display the keypad. Use the scroll keys to select a number, then press the **Commit** (⦿) key to enter the digit in the Age field (both scroll keys and the **Commit** key are on top of the unit). Repeat for each digit (up to 3 digits). Press the **Return** softkey to save the highlighted age and return to the Patient Information screen.

If you want to return to the Patient Information screen without saving the age, press the **Cancel** softkey.



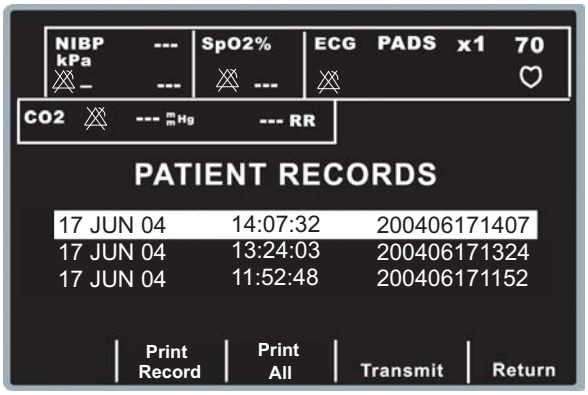
Patient Gender

Press the **Gender** softkey to toggle 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.

If you want to return to the Patient Information screen without saving the highlighted gender, press the **Return** softkey.

Patient Records

Press the **Patient Records** softkey to access the Patient Records screen. Use this screen to transmit or print specific 12-lead ECG records denoted by patient identification number (ID #), date, and time. Approximately 20 patient records can be stored on the E Series. You can erase 12 lead patient record memory by pressing and holding the summary button for 4 seconds and then pressing the Erase 12 Lead softkey.



Use the scroll keys on top of the unit to navigate through the list of stored 12-lead records.

Press the appropriate softkey depending on what you want to do:

- Print All — When this softkey is selected, the unit prints all stored 12-lead patient records on the strip chart.
- Print Record — When this softkey is selected, the unit prints the selected 12-lead patient record on the strip chart.
- Transmit — When this softkey is selected, the unit transmits the selected 12-lead patient record. The Transmission Setup screen appears as described in “12-Lead ECG Data Transmission” on page 4.
- Return — When this softkey is selected, the unit 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 in the next section, “12-Lead ECG Waveforms,” for a view of numbers 1, 2, and 4 above.

Optionally, you can configure the unit to print median complexes in a 4x3 format or standard data in a 2x6 format for faxes. (Refer to the *E Series Configuration Guide* 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 are preceded by the statement, “Poor data quality, interpretation may be adversely affected.” If this message prints, the analysis results may be invalid. Check for a 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.

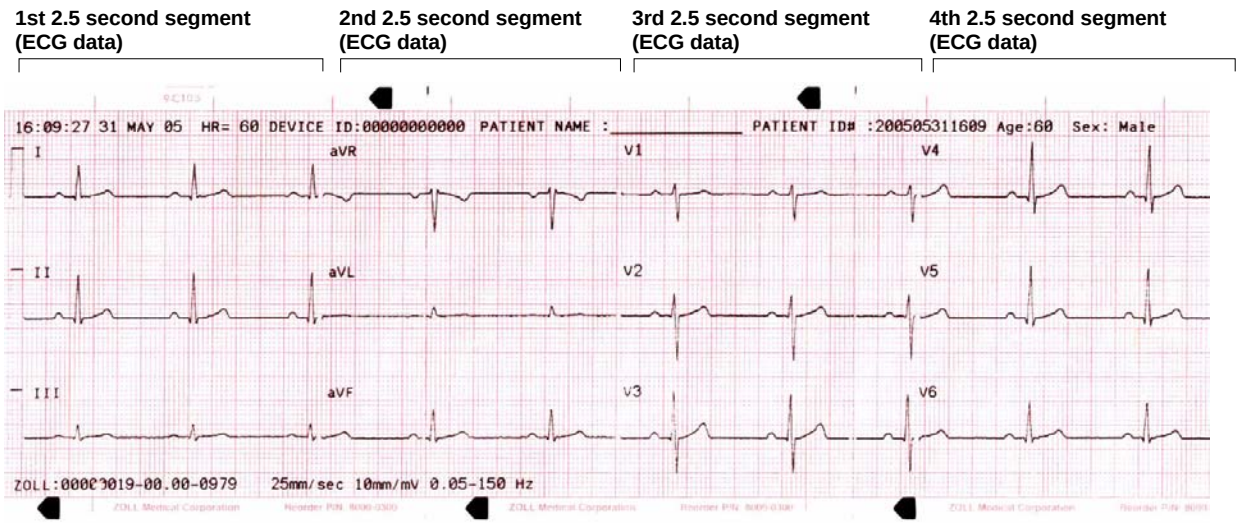
4x3 Format

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 the following figure). You can configure the report 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 E 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 E Series unit prints data acquired during the same time period (5, 7.5, or 10 seconds) for each set of ECG leads; the E 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. (The option applies only to real time 4x3 printouts and does not apply to reports or to the data stored to the data card.)

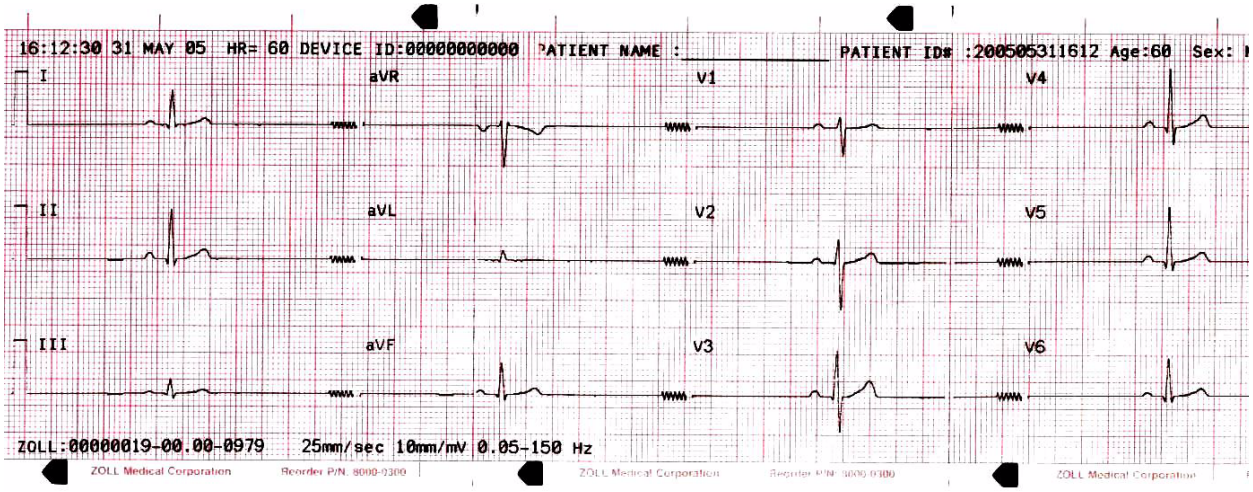
For information on how to change this default setting, see the *E Series Configuration Guide*.

Standard 12-lead printout is always in 4x3 format unless configured differently.



4x3 Median Complexes

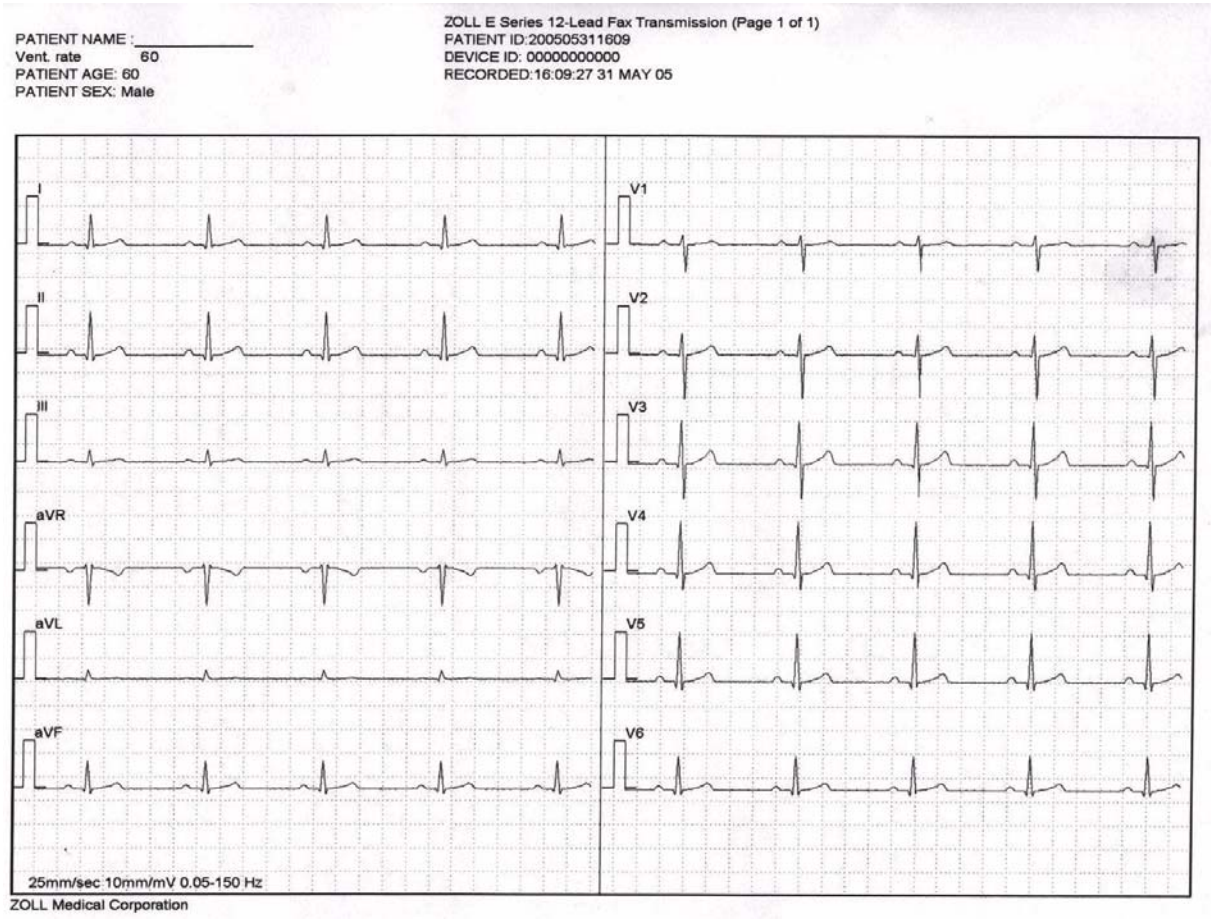
This format prints a single median beat for each of the twelve (12) leads. The median beat is computed by the 12SL algorithm and is denoted by a squiggle at the end of each median lead. You can configure the report for either standard or Cabrera print formats. 1 mV calibration pulses are printed at the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



2x6 Format (Fax Report Only)

The 2x6 Format 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 stripchart always prints in the 4x3 format.

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



Patient Information

DEVICE ID: 00000000000
RECORDED: 16:09:27 31 MAY 05
PATIENT NAME : JOE SMITH
PATIENT ID: 200505311609
PATIENT AGE: 60
PATIENT SEX: Male
Vent. Rate : 60
PR interval 166 ms
QRS Duration: 82 ms
QT/QTc 358 / 358 ms
P-R-T axes 54 43 47

Normal sinus rhythm
Normal ECG

*** Unconfirmed ***

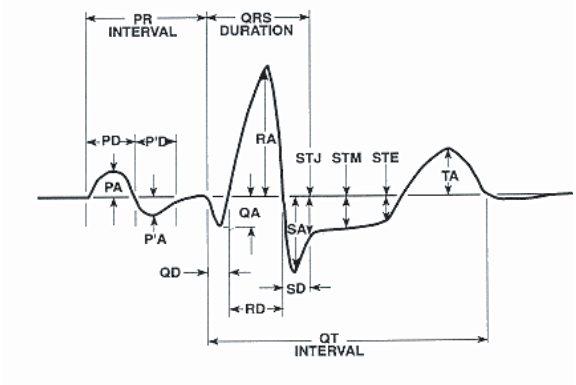
Measurements Matrix

You can configure the unit 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, you must change the default setting in the E Series device. (For more details, see the *E Series Configuration Guide*.)

	PA	PPA	QA	QD	RA	RD	SA	SD	RPA	RPD	SPA	STJ	STM	STE	TA	TPA
V1	-14	78	0	0	332	26	1093	58	0	0	0	-59	-49	0	97	0
V2	73	0	0	0	429	32	991	52	0	0	0	-25	-15	39	224	0
V3	102	0	0	0	566	44	829	40	0	0	0	-10	14	63	356	0
V4	122	0	0	0	620	48	832	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 160µV•ms, the wave is considered to be significant. If the area is less than 160µV•ms, the program considers the wave to be insignificant and does 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

ECG data can be viewed in three different ways:

- ECG Strip — The unit displays a 12-lead strip with 10 seconds of ECG data, in four staggered 2.5 second segments. For more information, see “4x3 Format” on page 10.
- Interpretation — The unit displays the results of interpretation of the ECG recording by the 12SL program.
- Measurements — The unit displays measurements based on all 12 leads.

The global measurements include heart rate, PR interval, QRS duration, QT, QTc, P axis, QRS axis, and T axis. These measurements are described as follows:

Measurement	Description
Heart Rate	Frequency is shown in beats per minute. Normal range is 60-100.
PR Interval	This time interval is between beginning of P wave and beginning of QRS complex. It is 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 beats per minute. 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	This is the axis of the P wave in degrees.
QRS axis	This is the 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	This is the axis of the T-wave.

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

Measurement	Description
PA, PPA*	These values are the minimum and maximum values of the P wave.
QA, RA, SA*	These values represent the absolute amplitude of the indicated wave.
STJ	ST level at J-point.
STM, STE	These are the ST levels at the middle and end point of the wave respectively.
TA, TPA*	These are the minimum and maximum values of the T wave.
QD, RD, SD	These represent the duration of the indicated wave in milliseconds.
RPA, RPD, SPA*	These are measurements that 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.

* All amplitudes are in µV (microvolts) or mm (at 10mm/mV) depending on the system setup.

For interpretation of these results, see the *12SL ECG Analysis Program Physician's Guide* (P/N 3001-0203).

Daily Operational Verification

Perform these steps daily to ensure proper operation of the E Series unit and 12-lead option. You will need either a 12-lead simulator or a volunteer “patient”.

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 simulator. If connecting to a patient, place ECG electrodes as indicated in “Electrode Placement” on page 3.
3. Connect the 12-lead cable to the connector located on the rear of the E Series.
4. Turn the E Series selector switch to **MONITOR**.
5. Select a normal sinus rhythm on the simulator (if using).
6. Press the **LEAD** button to cycle through each of the 12 leads.
7. Verify that good quality, artifact-free ECG signals are displayed and stabilized within 10 seconds on your E Series unit.
8. Verify *ECG LEAD OFF* is NOT displayed on the screen.
9. Verify *LOW BATTERY* is NOT displayed on the screen.
10. Verify the filter setting is set for 0.05 - 40 Hz (4x3).
11. Press and hold the **RECORDER** button for 3 seconds.
12. Verify appropriate ECG signals are printed. See “12-Lead Reports” on page 9 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 section is intended to help you identify and correct problems that arise during operation. If trouble persists after consulting this information, contact the ZOLL Technical Service Department for problems relating to the E 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
(Other locations) 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
The ECG baseline does not stabilize, the ECG is noisy, or the *NOISY ECG* message is displayed.	• 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. • Verify the gel of the electrode is not dry. Check expiration date on the electrode package. • Use Silver/Silver Chloride electrodes. • Verify that the patient cable is connected properly and held motionless. • Verify that the ECG snaps and connectors are clean. • Make sure that the patient is motionless. Support patient's limbs, if necessary. • Stop vehicle while acquiring the 12-lead ECG. • Verify correct filter (50 or 60 Hz) is selected in Configuration menu. • Inspect ECG cable. Replace the cable if damaged. • Change ECG filter setting to 0.05-40 Hz 4x3, and retry acquisition.
ECG LEAD OFF or *ECG VX LEAD OFF* message is displayed.	• Confirm proper ECG electrode and cable connections. • Prepare skin and replace electrodes. • Check the ECG cable continuity and replace the cable if you suspect it is damaged. **Note:** ECG signal may be temporarily out of range due to recent defibrillator discharge.
Unsuccessful transmission to fax machine (e.g., transmission stops before completion, signal disappears, etc.)	• Check modem connection to E Series. • Check modem connection to the phone jack or cellular phone. • Power cycle cellular phone. • Make sure that receiving fax is turned on. • Check the phone number and attempt to send again. • Check the telephone line (landline). 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 landline.

Symptom	Recommended Action
Unsuccessful transmission to MUSE.	• Check modem connection to E Series. • Check modem connection to the phone jack or cellular phone. • Power cycle cellular phone. • Verify with the hospital system administrator that the Catalyst MUSE system's modem is operational. • Check the phone number and attempt to send again. If multiple Catalyst MUSE phone numbers are configured, follow steps to attempt to transmit to an alternate number. • Check the telephone line (landline). 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. • Check the E Series configuration for valid Catalyst MUSE site and location identifiers.
FAX BUSY or *MUSE BUSY* message is displayed.	• Receiving phone line is being used. The E Series automatically attempts to transmit until the transmission is successful or the E Series operator presses the **Abort** softkey. • If transmitting to a Catalyst MUSE system and multiple Catalyst MUSE phone numbers are configured, press the **Abort** softkey and follow steps to attempt to transmit to another number.
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. • The E Series automatically re-transmits until the transmission is successful or the E Series operator presses the **Abort** softkey. • If transmitting to a Catalyst MUSE system and multiple Catalyst MUSE phone numbers are configured, press the **Abort** softkey and follow steps to attempt to transmit to another number.
FAX HANGUP or *MUSE HANGUP* message is displayed.	• Receiving phone is not receiving transmission. The E Series automatically attempts to transmit until the transmission is successful or the E Series operator presses the **Abort** softkey. • If transmitting to a Catalyst MUSE system and multiple Catalyst MUSE phone numbers are configured, press the **Abort** softkey and follow steps to attempt to transmit to another number.
FAX INTERRUPTED or *MUSE INTERRUPTED* message is displayed.	• Power cycle E Series unit, and follow steps to attempt to retransmit. • Contact ZOLL Technical Service department if problem persists.

Symptom	Recommended Action
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 E Series automatically attempts to transmit until the transmission is successful or the E Series operator presses the **Abort** softkey. If retransmission fails: • Check the modem connection to the E Series unit. • Power cycle the cellular phone. • If transmitting to a Catalyst MUSE system and multiple Catalyst MUSE phone numbers are configured, press the **Abort** softkey and follow steps to attempt to transmit to another number. • If transmitting to a Catalyst MUSE system, check that the Catalyst MUSE system's phone numbers are set up correctly. For more information, see the *E Series Configuration Guide.*
FAX NO DIAL TONE or *MUSE NO DIAL TONE* message is displayed.	• Check the modem connection to the E Series unit. • Check the modem connection to the phone jack or cellular phone. • Power cycle the cellular phone.
MODEM REQUIRED message is displayed.	No PCMCIA modem card is present. Insert PCMCIA modem card and repeat transmission attempt.
MUSE CANCEL message is displayed.	The E Series operator pressed the **Abort** softkey or turned the selector switch to DEFIB or PACER.
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 E Series unit. The data is incomplete or corrupted. Re-acquire 12-lead data, and attempt to retransmit.
DATA NOT READY / *SEND FROM PAT. REC.* message is displayed.	12-lead data is not yet ready for transmission. Select the 12-lead record from the Patient Records screen and retransmit.

APPENDIX A: Modem and Phone Setup

The E 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 E Series for phone transmission.

Modem

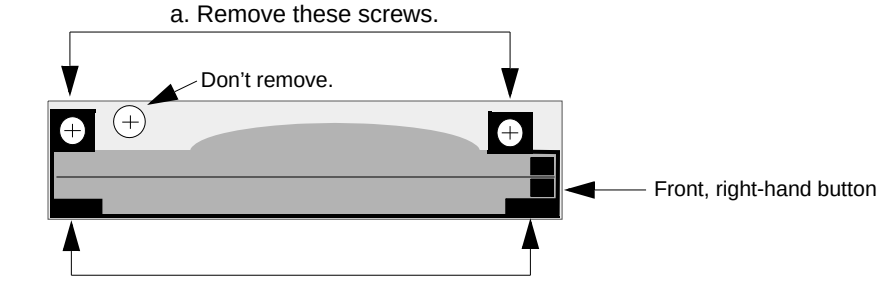
- When included, the E Series with 12-lead option ships with a cellular-ready PC card modem (domestic units only) installed in the front PCMCIA slot on top of the unit.
- The E Series with 12-lead option is also available with an approved GSM (Global System for Mobile communication) card modem (obtained locally for international customers).

Note: Do not attempt to insert the modem into the rear slot. Only the front PCMCIA slot supports modem communication.

Note: Before attempting to use modems other than those supplied with the unit, contact ZOLL Technical Support at (800) 348-9011. The E Series does not support all PCMCIA type modems.

The modem can be removed for service or cleaning as follows:

1. Open the PCMCIA cover, and complete steps a and b as shown.



2. Press down on front right button to remove modem card.

Reverse the sequence to install a modem card, making sure that the modem bracket.

is seated properly around the PCMCIA card connector before fastening the mounting screws.

Cables

- Not all cell phones transmit data reliably. See your local ZOLL Medical Corporation sales representative for a list of approved cell phones.
- A landline phone cable comes with modem-equipped E Series units. This cable connects to the E Series unit 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 E 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 phone model 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: +1 845 267-2655

  Fax: +1 845 267-2420

  International customers should contact their local ZOLL Medical Corporation sale 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 RJ-11 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.airdeskwireless.com

  Phone:+1 215 734 7000

  Fax:+1 215 734 8000

Configuring Phone Numbers

- Please see the *E Series Configuration Guide* for instructions on how to program automatic-dial phone numbers into the E Series unit.
- Manual phone number entry is described in “12-Lead ECG Data Transmission” on page 4.

Configuring the Modem for Cellular Phones

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

Satellite Phone Support

The E Series supports the transmission of Catalyst MUSE data via Motorola's Iridium 9505 satellite phone over the Iridium satellite network. The Iridium 9505 satellite phone has a built-in modem and requires an RS232 data connection. The RS232 connection to the E Series is achieved by replacing the PCMCIA fax/modem card normally used for fax/MUSE transmissions with a National Instruments PCMCIA-232 RS232 card.

The RS232 card and satellite phone support the transmission of MUSE data only. Fax transmissions are NOT available at this time via the RS232 card and satellite phone.

Operationally, there is no difference in the way MUSE transmissions are handled with the satellite phone versus the standard fax modem card and cell phone. You perform an Acquire or Select Patient Record operation, select a phone number, and press the **Transmit** softkey. However, you must understand the characteristics of satellite phone behavior. Transmissions must have an unobstructed line of sight to a satellite. This means that indoor transmissions will most likely not work. The satellite phone should generally be used outdoors or have an outdoor antenna.

Note that the display on the satellite phone should be used as an indicator of dialing progress. If a dialing sequence stalls, you should abort the dialing sequence and manually restart the transmission on the E Series unit.

When you attempt to fax data via satellite phone, the E Series detects the presence of the RS232 card and issues a general fax error.

Finally, you should also note that data card uploads are not handled via the National Instruments PCMCIA RS232 card. This function is accessed via the RS232 port on the back of the E Series unit. Dial-up clock synchronization is not available when the National Instruments PCMCIA RS232 card is installed.

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 your responsibility 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:

- The telephone number to which the device is connected.
- 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.
- The USOC telephone jack required (RJ-11, RJ-41, or RJ-45).
- 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 you will be required to correct the interference at your 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, you are 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 ZOLL Medical Corporation equipment 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.

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.

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APPENDIX B: 12-Lead ECG Data Transmission to Catalyst MUSE System

The ZOLL E 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 and hospital 12-lead data.

Prerequisites

Not all cell phones transmit to the Catalyst MUSE system reliably. See your local ZOLL Medical Corporation 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 E Series unit
- Set up the E 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 E 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 E Series device identifier also be configured. For more information, see the following sections in the *E Series Configuration Guide*:

- 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.

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