Braemar, Inc.

ER920W Wireless
Arrhythmia Event Monitor

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Recommended Separation Distances

Refer to the following table for recommended separation distances between the ER920W and portable and mobile RF communications equipment.

The ER920W is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the ER9xx can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ER9xx as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2.3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Braemar Limited Warranty

Braemar products are warranted to be free from manufacturing and material defects for a period of one (1) year from the date of shipment from Braemar to the original purchaser. This warranty does not apply to any product which Braemar determines has been modified or damaged by the customer.

Excluded from this warranty are expendable supply items including, but not limited to, electrodes, lead wires, patient cables and batteries.

Except for the express warranties stated above, Braemar disclaims all warranties including implied warranties of merchantability and fitness. The stated express warranties are in lieu of all obligations of liabilities on the part of Braemar for damages, including but not limited to, special indirect or consequential, arising out of or in connection with the use or performance of Braemar products.

Any action for breach of warranty shall be commenced within one (1) year of said breach or be forever barred. Any repairs made to the product, which are not covered by the warranty, shall be billed to the customer.

Device is to be serviced by Factory Authorized Technicians only. Do not attempt to repair, modify, or service the Braemar ER920W wireless arrhythmia monitor.

Do not attempt to open or tamper with recorder case. Opening the case will void recorder warranty.

Document Number: 600-0640-00
Revision: **D**
Date: November 2010

NOTE:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. 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. 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:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

The internal wireless radio operates within guidelines found in radio frequency safety standards and recommendations, which reflect the consensus of the scientific community. Braemar Inc. therefore believes the internal wireless radio is safe for use by consumers. The level of energy emitted is far less than the electromagnetic energy emitted by wireless devices such as mobile phones SAR value of 0.541W/kg max. **However, the use of wireless radios may be subject to governmental and business restrictions, including but not limited to air travel and hospital visitations.** If you are unsure of restrictions, you are encouraged to ask for authorization before turning on the wireless radio.

Radiofrequency radiation exposure Information

For body worn operation, this device has been tested and meets the FCC RF exposure guidelines when used with the Braemar pouch and accessories supplied or designated for this product. See Page 22 for a list of accessories and part numbers.

Use of other accessories may not ensure compliance with FCC RF exposure guidelines.

NOTICE: This device complies with part 15 of the FCC rules and with RSS-210 of Industry Canada. Operation of this device is subject to the following two conditions: (1) This device may not cause harmful interference; (2) This device must accept interference received including interference that may cause undesired operation.

Changes or modifications made to this equipment not expressly approved by (manufacturer name) may void the FCC authorization to operate this equipment.

Table of Contents

Overview

The ER920W Wireless Event Monitor is a battery operated, solid state, looping event recorder designed to record symptomatic heart arrhythmias. Event recording is activated by the patient or by automatic event detection.

The ER920W (1 or 2 channel) event monitor provides up to 30 minutes of total recording time and will operate as a simple looping event recorder for a minimum of 30 days with the Lithium Thionyl battery pack. It offers multiple programmed recording options allowing the physician to determine their own parameters. Selectable parameters include number of events, pre-event time, post-event time, audible operation, pacemaker detection, and arrhythmia detection.

The ER920W event monitor is enhanced with Arrhythmia Detection firmware which will capture and automatically record asymptomatic, infrequent, or elusive heart arrhythmia events such as Bradycardia, Tachycardia, Pause, and Atrial Fibrillation.

Once an event is recorded, the event ECG is automatically transferred via a digital cellular link or can be manually transferred transtelephonically (TTM) via a land line phone.

Indications for Use

The device is indicated for diagnostic evaluation of patients who experience transient symptoms such as; dizziness, palpitations, syncope, or chest pain. The device is intended to record cardiac activity associated with these infrequent and transient symptoms. Once data is recorded, patients transmit the recorded ECG data over the telephone or directly to a host PC for review by a licensed physician.

NOTE 1: At 80 MHz and 800MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the unit is used exceeds the applicable RF compliance level above, then the unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the unit.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

Precautions

A. Patient leads must be removed from electrodes before defibrillation.

B. Observe local laws for disposal of lithium batteries.

C. Do not leave the batteries in the Monitor when it is not in use. Damage from corrosion could result.

D. Patient should be instructed to avoid close proximity to heavy electrical equipment or other sources of electromagnetic interference.

E. Device should be powered with Factory supplier battery packs only. Do not use any other batteries, mix batteries, or use other power supplies in the Braemar ER920W wireless arrhythmia monitor.

F. Do not use cellular phone to transmit patient data.

G. Monitor is not for infant use.

H. No automatic analysis algorithm can replace data review by a qualified physician. Review and confirmation of analysis results is required.

Additional equipment classification information as required in EN 60601-1

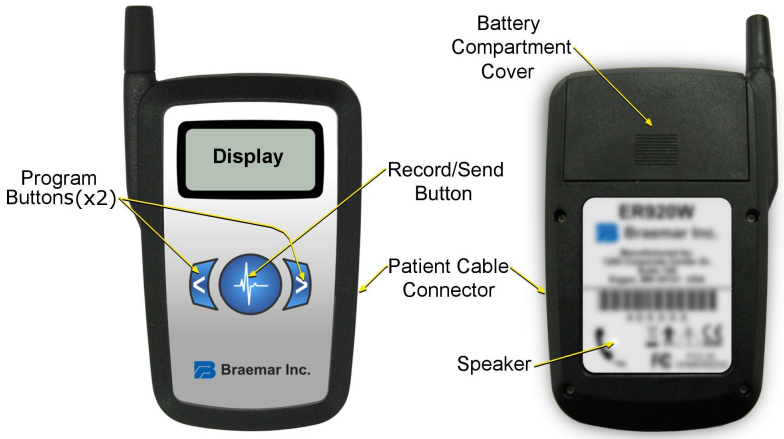
A. EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE

B. IPX0 Ordinary Equipment (enclosed equipment without protection against ingress of water)

C. Internally Powered Equipment

D. Mode of Operation - Continuous Operation

Monitor Components



Batteries	**ONLY use a 3.6V Lithium Thionyl battery pack. Insert into battery compartment observing polarity symbols.**
Patient Cable	To adjust, move plastic slip rings up or down to keep leads together. To lengthen, pull leads apart.

Caution: Only use a Braemar supplied 3.6 V Lithium Thionyl battery pack. Do not use any other battery in the ER920W. Use of any other battery pack or mixing batteries may cause overheating and/or damage the device. Use caution to observe correct polarity when inserting battery pack in the device. Failure to follow these instructions may cause damage to the device and will void the Manufacturer's Warranty. Please dispose of exhausted battery packs according to local laws.

U.S. Federal law restricts this device to sale by or on the order of a physician.

Electromagnetic Emissions

Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The ER920W uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The ER920W is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Electromagnetic Immunity

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Specifications

Functional

ER920W Wireless	1 or 2 channel
Max Number of events	30
Sample rate	256 samples per second
User interface	LCD display and sound

Memory

Max event time	
One channel	30 minutes
Two channel	30 minutes
Max total record time	
One channel	30 minutes
Two channel	30 minutes
Type	Flash
Data retention	Non-volatile

Physical

Dimensions	2.82"x 4.33" (5.16" w/antenna) x .90" (71.6mm x 109.9mm [131.06mm] x 22.86mm)
Weight with batteries	5 oz.
Enclosure	Molded plastic
Operating position	Any orientation

Electrical

Input impedance	2M min.
CMR ratio	60dB
AC signal range	+/- 3mV
DC signal range	+/- 300mV
Resolution	23uV (8bits)
Frequency response	.05Hz to 40Hz
FCC ID	HHMER920W-AF
IC ID	9158A-ER920WAF

Environmental

Operating temperature	0°C to +45°C
Non-operating temperature	-20°C to +65°C
Operating humidity	10% to 95% (non-condensing)
Non-Operating humidity	5% to 95%

Transtelephonic Transmission

Transmit carrier	1900Hz
Carrier deviation	100Hz/mV

Battery

Type	(1) 3.6V Lithium Thionyl Battery Pack
Life	300 transmissions, typically 30 days min.
	Remove batteries during storage

Warranty

12 months from shipment

Setup Steps

This manual is designed to allow a technician to follow the instructions page by page to set up the ER920W. Here is the general layout:

1. Connect leads and electrodes to patient.
2. Prepare Monitor for recording.
   A. Select program settings you want to use.
   B. Erase all previous events.
3. Connect Patient Cable to Monitor.

Electrode Application and Placement

For each electrode lead wire:

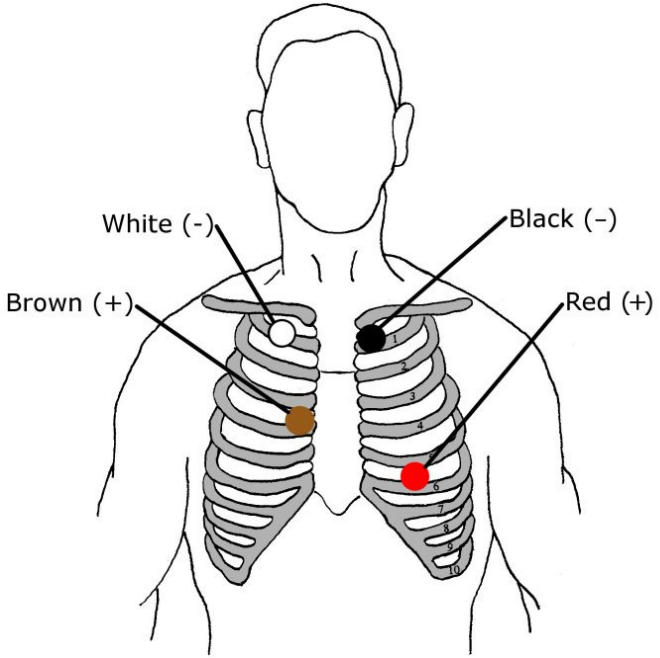
1. Check the Patient Cable for any damage. Do not use damaged or broken cables.
2. Snap the electrode onto the lead wire.
3. Remove the protective backing from the adhesive side of the electrode.
4. Apply the electrode to the patient's skin per Electrode Placement diagram in this manual or as instructed by the physician.

   NOTES:

   A. The ER920W will support either a 1 Channel or 2 Channel cable.
   B. It is recommended that trained medical personnel instruct the patient in the proper application of electrodes.
   C. Use good quality long term electrodes. Braemar recommends the use of low impedance Holter electrodes. Instruct patient to apply fresh electrodes regularly. (Usually on a daily basis.)
   D. Proper preparation of the patient's skin is absolutely essential for obtaining a quality ECG recording. The skin surface where the electrodes will be placed should be cleaned with alcohol, allowed to dry, and abraded.
   E. Any loose electrode needs to be replaced.

1 and 2 Channel (4 Lead) Electrode Placement

This is a typical electrode placement. Refer to Analysis System software and the physician for recommended positioning.



1 and 2 Channel Electrode Placement
Use only Channel 1 if you have a single channel cable.

Channel 1 = White and Red (V5 vector)
Channel 2 = Black and Brown (V1 vector)

Equipment Symbols

Symbol	Description
	Type B Applied Part
	Attention: Consult accompanying documents.
SN	Serial Number
	Date of Manufacture
	Manufacturer name and address

Manufacturer:
Braemar, Inc.
1285 Corporate Center Drive, Suite 150
Eagan, MN 55121 USA

Phone: 800.328.2719
651.286.8620
Fax: 651.286.8630
E-mail: service@braemarinc.com
Web: http://www.braemarinc.com

Contact Braemar for further technical information.

Service and Maintenance

Cleaning

Routine cleaning should be performed before each patient use. Remove the batteries before cleaning the recorder. Clean the battery terminals with a soft dry cloth. Dampen a soft cloth with mild detergent and water to clean the recorder, lead wires, and belt clip.

Remove any adhesives from the patient lead wires with an adhesive tape remover solution or swab. Use a mild disinfectant. Do not use alcohol or acetone on the lead wires since they could stiffen and the insulating plastic could crack.

Service

If there is a problem with the Monitor, refer to the Troubleshooting section and review the symptoms and solutions. If additional assistance is required contact customer support via phone, Fax or E-mail listed on the next page. Call customer support before returning a Monitor to make shipping arrangements.

A. Note there is not any preventative inspection or maintenance that can be performed by the end user.

Service Items and Accessories

Description	Part Number
Patient lead, 1 channel, Shielded	350-0173-09
Patient lead, 2 channel, Shielded	350-0173-10
Pouch	100-1894-001
Lanyard	350-0304-00
Operator manual	600-0640-00
3.6V Lithium Thionyl Battery Pack	350-0294-00

NOTES:

A. Only accessories listed above are meant for use with the Monitor.

B. Dispose of batteries in accordance with Federal, State, and Local laws.

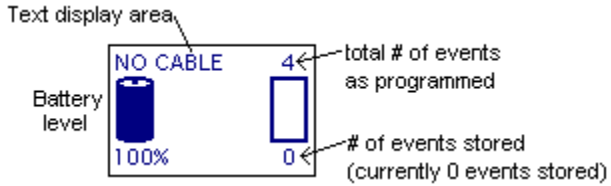
Monitor Preparation

1. **General setup:**

Remove the Patient Cable if it is connected to the Monitor. Open the battery compartment by sliding battery door downward. Install the battery pack of AA Lithium Thionyl batteries. Observe proper battery polarity. The Monitor will sound rising tones after completion of power up. After a few seconds, the display will show the battery level and number of events stored.

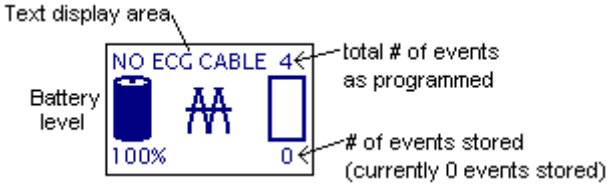
The battery level should read 100% for the battery pack and should be near 100% with a fresh battery pack of AA Lithium Thionyl batteries. The number of events stored does not matter at this point.

When the device detects the battery it is ready to monitor, record, and send patient data files via wireless communication and the following screen will be displayed:



Conditions which may cause the "AA" symbol (cellular communication has been disabled) to be displayed:

- Low batteries
- Initialization with cell tower failed
- Wireless setting in program menu is set to "Off"



2. **Enter programming mode:**
   A. Push and hold **both** program buttons on the front of the Monitor until an audible tone is heard.
   B. The Monitor will then display an information screen. Press the RECORD/SEND button to get to the programming mode screen.

General Notes:

A. To leave the programming mode without saving your changes, remove the batteries.

B. If you enter the programming mode, events stored in the Monitor are always erased when the Monitor restarts and a Patient Cable is connected.

NOTE:

- **Be sure to send all stored events prior to entering programming mode to avoid losing stored patient files.**

C. All previously stored events and settings are erased when you select EXIT on the last programming screen.

D. The Monitor always highlights the DEFAULT option when entering programming mode even if the CUSTOM option was last used. Whatever option was used for a previous recording will continue to be used.

E. Previously saved settings are displayed when viewing the CUSTOM programming screen.

F. Factory default settings are indicated by a "✳" (asterisk) in front of the setting.

G. Use the program buttons to view and select program settings options; THEN press the RECORD/SEND button to confirm the selected setting. Pressing RECORD/SEND also advances the screen to the next program setting.

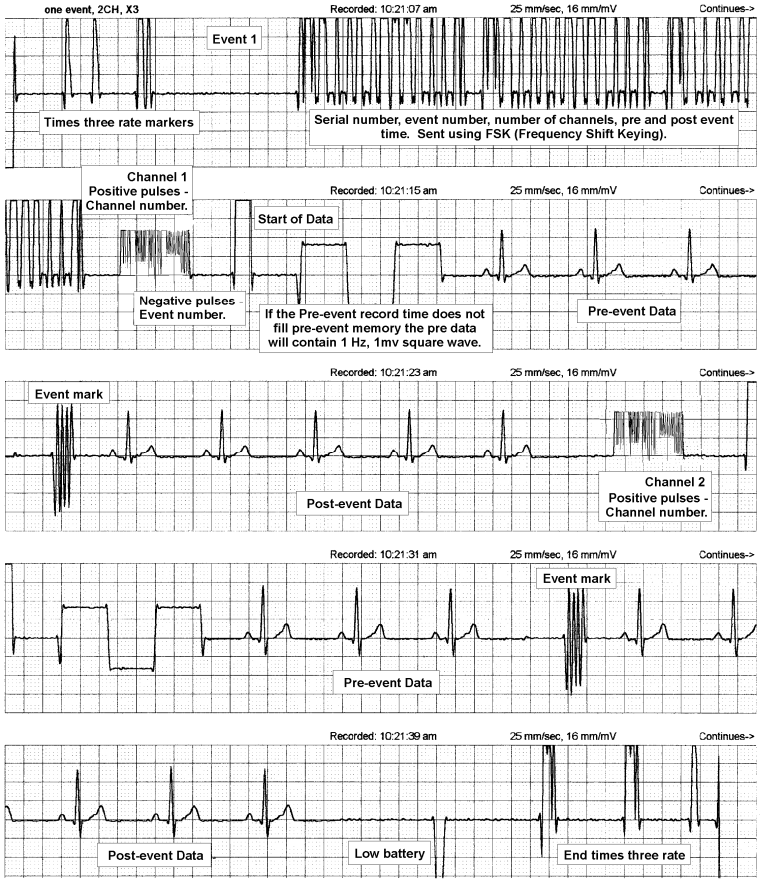
H. Lead loss detection is enabled all the time.

I. The number of channels a Patient Cable contains will determine the number of channels the Monitor will record.

J. When a new monitoring period is started, a fresh pack of AA Lithium Thionyl batteries should be used.

Event Markings

The following shows typical event markings that are generated by the Monitor and appear on the receiving station strip chart.



Troubleshooting (page 2 of 2)

Displays “Stopped” at top of LCD	Batteries were pulled during programming.
	At completion of TTM (sound) data transmission, unit is “stopped”. NOTE: Neither condition is a problem. Power cycle or finish programming.
Noise artifact on recorded ECG at receiving center	Mouthpiece of phone must be close to the Monitor speaker hole.
	Check telephone connection. Listen to phone line before sending event(s) to ensure there is no noise.
	Have patient call back and send ECG again.
	Have patient try another phone.
Noise artifact on recorded ECG at patient location	Electrodes must be securely attached to patient.
	Patient should remain still while recording.
	Replace Patient Cable. Pulling on lead wires may damage cable.
	Verify the recording did not take place near a source of electromagnetic interference (fluorescent lights, computer monitors, or household appliances).
	Move electrodes slightly to the right or left of the original location.
All or groups of timestamps for recordings are the same	If the inadvertent loss of power occurs, all the timestamps in the FSK will reset to the time the unit powered back up. Subsequent recordings will have time stamps relative to the power up time.
Falling tone	Transmission complete.
Rising tone	Ready to record.
displayed (cellular communication has been disabled)	Low batteries. Not enough power to register cellular modem with tower. Try new batteries.
	Initialization with cell tower failed. Cycle battery power. Ensure unit turns off completely. Re-insert batteries. If condition continues with different batteries or additional power cycles, contact customer service.
	Wireless setting in program menu is set to OFF. Turn ON.

Note about Arrhythmia and AFIB detection:

A. To change Arrhythmia and AFIB settings you must access the CUSTOM program option.

B. The Arrhythmia and AFIB algorithms can be used independently.

C. There is no guarantee arrhythmia detection algorithms will detect all episodes of arrhythmia. For maximum efficacy, use the most sensitive settings.

Notes about Sound:

A. Lead loss sound overrides the POST-EVENT SOUND setting.

B. If the Monitor detects lead loss during a recording, the Monitor will produce an audible sound of the event until the recording is complete. You can mute this sound by using the AUDIO setting **after** the recording is complete.

C. The AUDIO setting can only be accessed **before or after** an event is recorded. **Trying to access the AUDIO setting during a recording will cause the recording to stop.**

D. The AUDIO setting controls many of the sounds produced during the monitoring period. Audio may be turned ON or OFF. The AUDIO screen can be accessed during normal monitoring conditions (Patient Cable inserted) by pressing only one of the programming buttons until an audible sound is heard. The AUDIO screen will exit after 10 seconds of inactivity.

E. The AUDIO setting defaults to ON every time the Monitor is powered up.

F. The AUDIO setting defaults to ON every time the Patient Cable is removed. This is to enable the Monitor to send events to the receiving center.

3. **Choose program:**

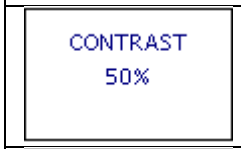
   Choose either the DEFAULT or CUSTOM option. The CUSTOM option allows changes to all of the following settings.

   NOTES:

   A. Factory default settings in the Monitor are indicated by a "✳" in front of the setting.

   B. Choosing the DEFAULT option will program the monitor with the factory default values, erase previous patient data, and restart the monitor.

Programming settings:

Display	Option	Description
	DISPLAY CONTRAST Default = NA	Set the contrast of the display. A higher number will cause darker text on the screen.
	PRE-EVENT TIME Default = 30 sec	Seconds of ECG data stored before event activation time. 300 seconds total can be split between Pre and Post events. (Programmable 5-295 sec in 5 second increments)
	POST-EVENT TIME Default = 30 sec	Seconds of ECG data stored after event activation time. (Programmable 5—295 seconds in 5 second increments)
	POST-EVENT SOUND Default = OFF	ON = Sound on while recording during the Post-Event time. OFF = Sound off while recording an event. See Notes about sound for additional information.

Troubleshooting (page 1 of 2)

Symptom	Recommended Solution
No display	Ensure batteries are inserted with correct polarity.
Cannot enter programming mode	The Patient Cable must be removed and the batteries installed. Then follow instruction in manual.
Cannot access AUDIO setting, Patient wants to mute Monitor.	A good connection must be made from the Monitor to the patient to be able to access the AUDIO setting.
	While monitoring, press and hold **only one** of the programming buttons until an audible sound is heard to access the AUDIO setting.
	AUDIO setting cannot be accessed during a recording. Wait until end of recording, then access AUDIO screen.
No phone ring at end of recording	AUDIO setting is turned OFF, which mutes most sounds.
No beep when inserting Patient Cable	Ensure patient electrodes/leads are connected to patient properly. Is the Patient Cable damaged in some way?
	Ensure Patient Cable is inserted completely.
	Patient Cable has more channels than Monitor can use. Match the number channels for the cable and Monitor.
Will not record	Memory full-Phone Ring. Follow instructions To Send and Erase Events.
	Ensure Patient Cable is inserted completely.
	Ensure RECORD/SEND button is held until an audible sound is heard.
Monitor stops recording.	Holding any button for two seconds while recording will cause the Monitor to stop recording. This includes trying to access the AUDIO setting.
Siren (alternating) tone while recording	There is not a good connection. Check that electrodes/leads have a good connection to patient and cable is plugged into Monitor.
Monitor restarts and erases stored events	Changing the Patient Cable to a different number of channels tells the Monitor to restart and erase all events.
Phone ring sound every hour	Memory has event(s) to be transmitted to the receiving center.
Phone ring sound every minute for 10 minutes	Memory is full; follow instructions To Send and Erase Events.
Phone ring sound when RECORD/SEND button is pushed	Memory is full; follow instructions To Send and Erase Events.
Phone ring sound once	An event is already stored in memory at start up, also heard at the end of a recorded event. Follow instructions To Send and Erase Events.
Three beeps every five minutes with cable inserted	Batteries are low. Replace batteries and/or clean battery contacts.
No information received by receiving center	Make sure **mouthpiece** of phone is directly over Monitor speaker.
	Ensure RECORD/SEND button is held for two seconds.

4. Follow receiving center instructions.
   A. When instructed, place the telephone **mouthpiece** over the Monitor speaker hole.

   B. Push the RECORD/SEND button until you hear audible sounds. "SENDING" will be shown in the upper left hand corner of the display while the recording is being sent.
      - A falling tone will sound when the transmission is complete and "STOPPED" or "MEMORY FULL" will be shown in the upper left hand corner of the display.
      - Pressing RECORD/SEND during transmission will abort the transmission. Pressing RECORD/SEND again will re-send the recording.
5. When instructed that the events have been sent successfully, it is OK to erase events by reinserting the Patient Cable. (The Monitor will restart and you will then hear a rising tone.)

Receiving a Text Message:

The ER920W monitor can receive text messages from the technician. Messages up to 40 characters can be displayed on the LCD of the recorder. This allows communications back to the patient.

NOTE:

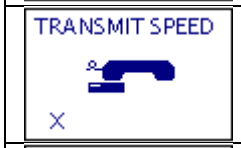
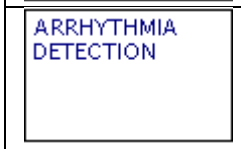
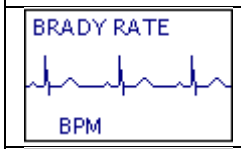
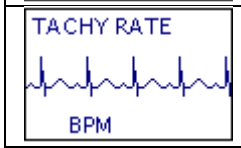
A Text message received by a recorder will initiate a beeping sequence alerting the patient of a new incoming message. The TEXT message and beep sequence can only be disabled by the monitoring center or by pressing one of the programming buttons (arrow button) until the sound is muted.

Erase Events:

Events are automatically erased after a successful digital transmission. There is not any patient interaction required for this erasure to occur.

Manually Erase Events:

1. Insert the Patient Cable. The Monitor will restart, erase the stored events and emit a rising tone.

Display	Option	Description
	HOURLY REMINDER Default = ON	ON = Ring every hour when an event is stored in memory. OFF = Do not remind patient an event is stored in memory.
	PREVIEW TIME Default = 30 sec	The number of seconds the ECG signal is displayed for each channel when the patient cable is inserted.
	TRANSMIT SPEED Default = 1X	File transmission speed for TTM data transfer to Central Receiving station.
	PACEMAKER DETECTION Default = ON	Program Pacemaker detection ON/OFF.
	ARRHYTHMIA DETECTION Default = ON	Program Arrhythmia Detection ON/OFF. Select "ON" to program, Brady Rate, Tachy Rate, and Pause duration rate thresholds.
	BRADY RATE Default = 45 bpm	(Arrhythmia Detection must be on to access this function)
	TACHY RATE Default = 160 bpm	(Arrhythmia Detection must be on to access this function)

Continue on next page

User Defined options continued

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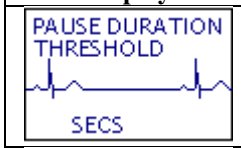
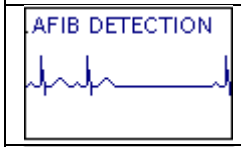
Display	Option	Description
	PAUSE DURATION THRESHOLD Default = 3.0 sec	(Arrhythmia Detection must be on to access this function)
	AFIB DETECTION Default = ON	-AF devices only-
	# OF EVENTS	Total number of events the monitor will store. The maximum number allowed is dependent on Pre and Post Event times.
	WIRELESS MODEM Default = ON	Select wireless modem ON/OFF. "OFF" requires TTM file transmissions.
	EXIT OR REVIEW PROGRAM	See step about leaving programming mode for information.

4. **Exit program mode and erase events:**

   Choose EXIT from the last programming mode screen and press the RECORD/SEND button. The Monitor will restart.

NOTE:

A. Choosing EXIT will erase all stored events and save your settings over the top of previous program settings. Choosing REVIEW will allow you to changes program settings.

Send Data via wireless transmission:

In most cases, events are automatically downloaded to the receiving center via digital cellular link. There is no patient interaction required for this transmission to occur. One event will be stored before it is sent to the receiving center.

When the device is transmitting an event, a value (*3 for example) will be displayed in the upper right hand corner of the LCD. This value represents the quality of the signal strength which the modem has detected when transmitting the event. This value has a range of *0 - *5, *5 being the most robust signal possible.

Upon successful transmission of data, the device will connect to the server according to the table below to check for any text messages.

Hours since Last ECG:	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10+**
Reconnect time: Once every	15 min	30 min	60 min	60 min	60 min	60 min	60 min	60 min	60 min	24 hrs

If a text message is received in the first hour since the event was sent, the device will reconnect to the server every 5 minutes to check for additional commands or other text messages, otherwise the communication protocol will follow the above table.

If an appropriate cellular signal is not present and the transmission of the event was unsuccessful, the monitor will try an additional 3 times, once every 5 minutes. If communication to the server fails three times the device will output a phone ring alerting the patient of a stored event. The patient can then send the event to the receiving center manually as described below.

If the patient does not send the event manually and the event is still stored, the device will retry to connect to the server after 60 minutes.

To Manually Send Events via TTM:

1. Remove the Patient Cable from the Monitor.
2. Set the Monitor on a flat surface with the speaker hole up.
3. Call the receiving center.
   A. Cell phones and VOIP phones **do not** work for the transmission.

To Record:

1. Press the RECORD/SEND button until an audible sound is heard, then release.

   NOTES:

   A. To stop a recording, press the RECORD/SEND button again until an audible sound is heard.

   B. "RECORDING" will flash in the upper left hand corner of the display.

2. Hold as still as possible during recording but continue breathing.
3. The recording is complete and ready to send when a phone ring is heard from the Monitor.

   NOTES:

   A. The display will also show that an event is stored in the Monitor. If the memory is full, follow instructions To Send and Erase Events

   B. You can mute many of the sounds from the Monitor by pressing only one of the programming buttons until the speaker is displayed. This screen allows you to select whether AUDIO for the Monitor is turned ON or OFF, or will immediately mute the device if it is displaying a message from your service.

   C. The AUDIO setting defaults to ON every time the Monitor is powered up.

   D. The AUDIO setting defaults to ON every time the Patient Cable is removed. This is to enable the Monitor to send events to the receiving center.

Automatic Record:

If Arrhythmia Detection is ON and an event is detected, the Monitor will beep at the start of the recording only if the wireless transmission option is not active. When the recording is complete and ready to send a phone ring will be heard from the Monitor if the patient must send the recording manually via TTM. An event will show on the display under all circumstances.

A. The last event location is always reserved for a manual recording.

Alternate method to erase events:

If you don't want to enter the programming mode, you can also erase events by the following sequence.

A. Remove the Patient Cable.

B. Hold the RECORD/SEND button until audible tone is heard. You will hear the transmission of any events stored in the Monitor. At the end of the transmission you will hear a falling tone and the Monitor will display STOPPED in the upper left.

C. Inserting the Patient Cable at this time will erase all events and restart the Monitor.

5. **Connect the patient:**

   A. At this time, the patient leads should be connected to the electrodes and the electrodes should be connected to the patient.

   B. Insert the Patient Cable into the Monitor.

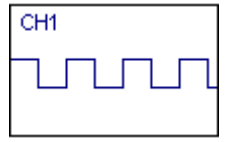
   NOTE:

   - If the patient is connected correctly, the Monitor will sound one beep for a single channel cable or two beeps for a two channel cable.

   C. View the display just after the Patient Cable is connected. It will show the signal from each channel of the cable.

   NOTES:

   - There will be an accompanying beep for the channel number displayed.
   - The Monitor will not respond to any button presses other than Record Event during the preview time.
   - Square wave will be displayed on the LCD if a good patient connection is not established. An adequate connection with good ECG signal must occur before the ER920W wireless arrhythmia monitor initiates monitoring.

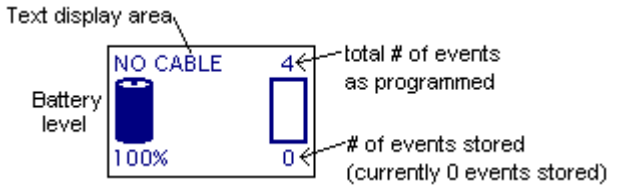


6. **The Monitor is ready to record events.**
   A. The general settings of the Monitor are displayed during operation by the number of dots after the word "MONITORING" shown on the display.

Display	Setting
MONITORING	No Arrhythmia or AFIB
MONITORING.	Arrhythmia only
MONITORING..	Arrhythmia and AFIB
MONITORING...	AFIB only

Patient Operating Instructions

Display overview:



To Connect Monitor:

1. Snap lead wires onto electrodes first, and then apply electrodes according to physician instructions.
2. **Reapply fresh electrodes daily.**
3. Insert the Patient Cable into the Monitor.

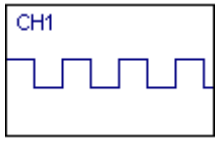
   NOTES:

   A. Depending on the cable, there should be a single or double beep that indicates a good patient connection. If no beep is heard, double check cable connections.

   B. Viewing the display just after the Patient Cable is connected will show the signals from each of the channels. There will also be an accompanying beep for the channel number displayed.

   C. The Monitor will not respond to any button presses other than Record Event during the preview time.

   D. Square wave will be displayed on the LCD if a good patient connection is not established. An adequate connection with good ECG signal must occur before the ER920W wireless arrhythmia monitor initiates monitoring.



   E. Monitor is now looping and ready to record.