Braemar, Inc.

Fusion Wireless Recorder

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.

Excluded from this warranty are expendable supply items including, but not limited to, electrodes, lead wires, patient cables and batteries. This warranty does not apply to any product which Braemar determines has been modified or damaged by the customer.

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.

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DRAFT

Table of Contents

Overview

The Fusion Wireless recorder is a battery operated, solid state recorder designed to record symptomatic heart arrhythmias.

The Fusion recorder provides up to xx days of total recording time for 3 channels, xx days of total recording time for 1 or 2 channels.

The Fusion recorder 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. If a digital cellular link is not available, the event ECG can be transferred by Bluetooth to a phone line via a Home Link Bluetooth modem.

Precautions

A. Patient leads must be removed from electrodes before defibrillation.
B. Observe local laws for disposal of batteries.
C. Do not leave the batteries in the recorder 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. Use only the provided battery pack. Observe polarity when inserting
F. Recorder is not for infant use.
G. No automatic analysis algorithm can replace data review by a qualified physician. Review and confirmation of analysis results is required.
H. Patients should seek immediate medical attention if they experience symptoms that concern them.

Disclaimer

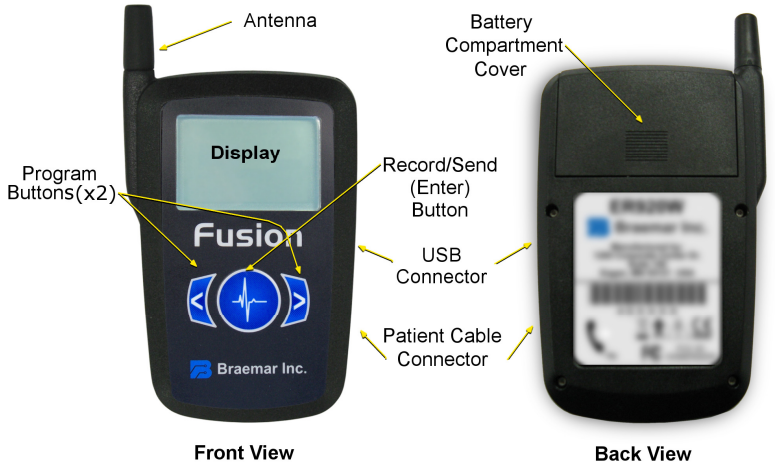
Operation of the Fusion recorder may be subject to governmental and business restrictions, including but not limited to air travel and hospital visitations.

This device is approved for use only in the United States of America

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

Recorder Components



Batteries	3.6V AA Lithium 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: U.S. Federal law restricts this device to sale by or on the order of a physician.

Setup Steps

DO NOT ENROLL PATIENT IN SOFTWARE UNTIL INSTRUCED TO DO SO

This manual is designed to allow a technician to follow the instructions page by page to setup the Fusion recorder. Here is the general layout:

The Fusion recorder is preprogrammed from the factory for default settings. The device is fully programmable through the Fusion Wireless Monitoring System Software. Please refer to the Fusion Wireless Monitoring System Software for programming capabilities and options

1. If the recorder contains batteries, and/or a cable remove them and insure the screen is blank before proceeding
2. Install fresh batteries into recorder. Install only AA Lithium battery packs provided by Braemar. Observe proper battery polarity when installing. The battery indicator resets to indicate a full capacity battery each time the batteries are inserted. For an accurate indication you must install fresh unused batteries.
3. Inspect LCD Screen. There are several screens that you may be greeted with when powering on a recorder. This section covers each of those screens.

   "No cable" screen: The recorder does not have any previous patient data and you can proceed to step 4.

   "Recording…" screen: The recorder is still recording data, you must stop the recording and erase all the data before setting up the recorder for the next patient.

   Press the left and right buttons together and it will prompt you if you want to stop the recording.

   Press the Enter button to stop recording the data and the "Recording Complete" screen will appear.

   Continue to erase the data by following the "Recording Complete" screen steps.

"Recording Complete" screen: The recorder still has data in it, you must erase all the data before setting up for the next patient.

Press the left and right buttons together and it will prompt you to "Erase Data".

Press the Enter button to erase the data. The display will have the message "Recorder Empty".

Continue setting up the recorder by following to the "Recorder Empty" screen steps.

"Recorder Empty" screen: The recorder is ready to be reset.

Remove the batteries

Return to step 2

4. Apply electrodes to patient
5. Connect snaps to electrodes
6. Plug cable into recorder
7. Observe LCD main menu screen
8. Verify lead status to be OK as described below
9. Verify ECG signal is OK as described below
10. Remove Batteries
11. Enroll patient on software via Enrollment Tab using the Fusion Wireless Monitoring System Software
12. Verify Enrollment by looking for yellow dot in the Patients Tab using the Fusion Wireless Monitoring System Software
13. Insert Batteries into the Fusion recorder
14. Verify the recording starts automatically by inspecting the LCD for the Recording…. screen
15. Verify yellow dot has been changed to two green dots in the Patients tab using the Fusion Wireless Monitoring System Software
16. Set up is complete and the recoding has been successfully started

Electrode Application and Placement

For each electrode lead wire:

1. Snap the electrode onto the lead wire.
2. Remove the protective backing from the adhesive side of the electrode.
3. Apply the electrode to the patient's skin per Electrode Placement diagram in this manual or as instructed by the physician.

   Notes:

   A. It is recommended that trained medical personnel instruct the patient in the proper application of electrodes.

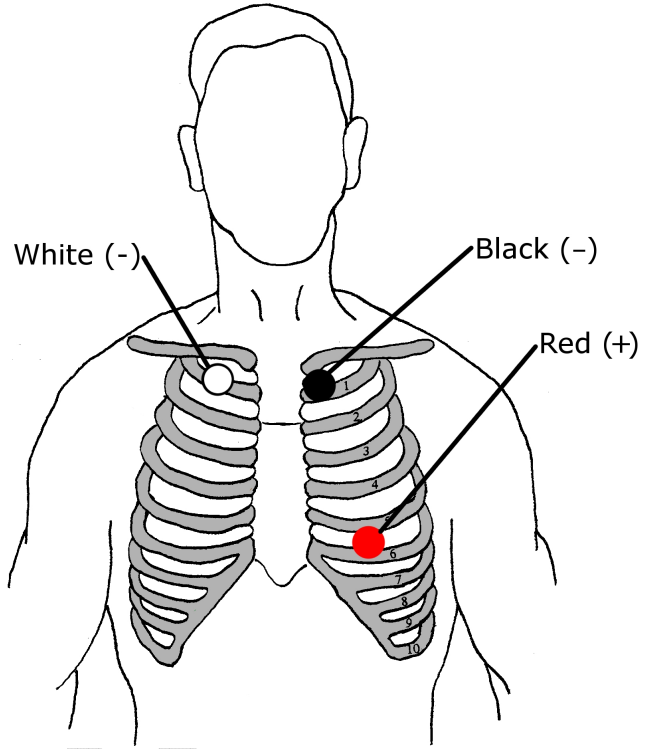
   B. Use good quality long term electrodes. Braemar recommends the use of low impedance Holter electrodes. Instruct patient to apply fresh electrodes regularly. (Usually on a daily basis.)

   C. 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 abraeded.

   D. Any loose electrode needs to be replaced.

3 Lead 2 Channel Electrode Placement

This is a typical electrode placement for a 3 lead 2 channel patient cable.

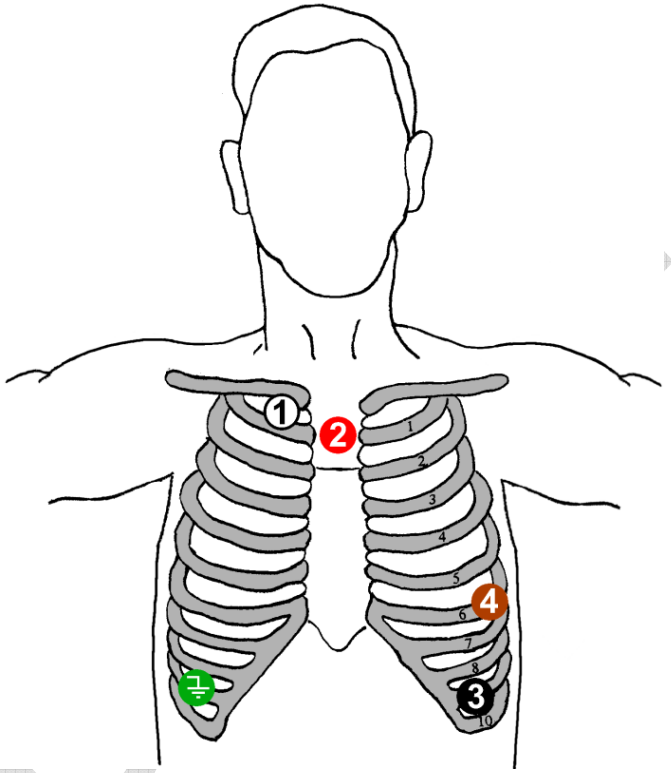


Channel 1 = Red (1+), White (1-),

Channel 2 = Black (2+), White (1-)

3 Channel (5 lead) Electrode Placement (1st option)

Five color-coded leadwires are used to create a 3-channel ECG recording. This is a typical electrode placement. Refer to your Analysis System software and the physician for a recommended position.



5 Lead Electrode Placement

#	Channel	Color	Location
1	3-	White	Next to the right Manubrium border on the Clavicle
2	1-, 2-	Red	Centered on the Manubrium
3	2+, 3+	Black	Lower left rib margin over bone.
4	1+	Brown	Left Anterior Auxiliary line on the 6th rib
5	⏚	Green	Lower right rib margin over bone.

3 Channel (5 lead) Electrode Placement (2nd option)

Five color-coded leadwires are used to create a 3-channel ECG recording. This is a typical electrode placement. Refer to your Analysis System software and the physician for a recommended position.

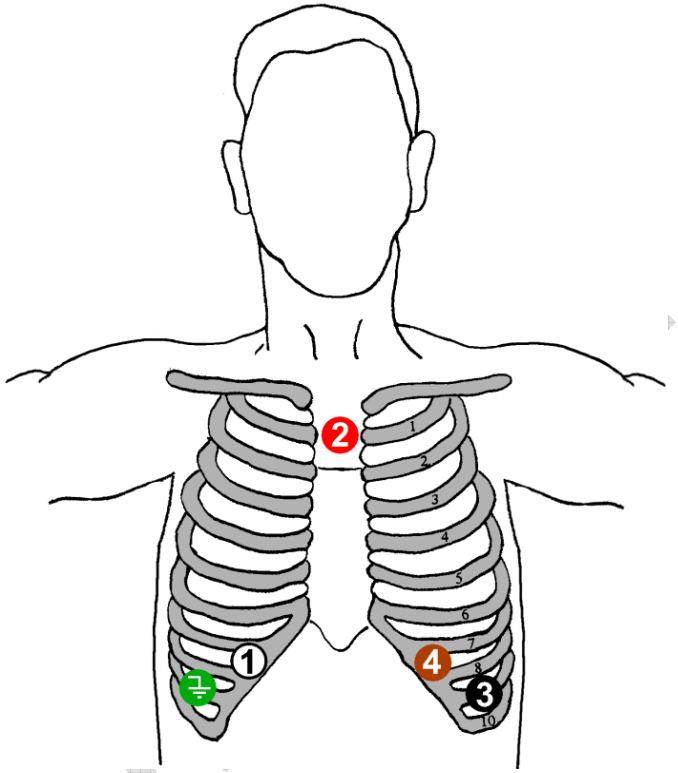
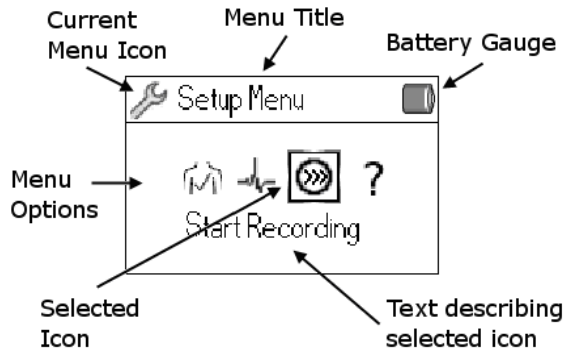


Figure 4 - 5 Lead Electrode Placement

#	Channel	Color	Placement
1	3-	White	Right side below the V1 position, at the bottom of the rib cage
2	1-, 2-	Red	Center on the Manubrium, the top of the sternum
3	2+, 3+	Black	Left side at the V5 position, on a rib
4	1+	Brown	Left side at the V3 position, on a rib
5	⏚	Green	Right side opposite V5 position.

1. **Patient cable connection**

   At this time, the patient leads should be connected to the electrodes, the electrodes should be connected to the patient, and the patient cable should be inserted into the recorder.



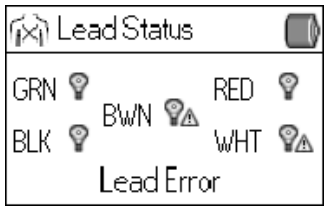
Setup Menu Overview

2. **Checking lead connections:**

   Using the left and right arrow buttons, select Lead Status (or icons) and press the Enter button. Check the status of the lead so make sure each of them has a good connection.

   - Leads with good connections display
   - Leads with poor connections display
   - "Lead Error" will also display at the bottom of the screen

   At least two leads must be connected to see the Lead Status. If there are less than two leads present, a "No Cable" message is displayed. Press the Enter button to return to the Setup Menu.



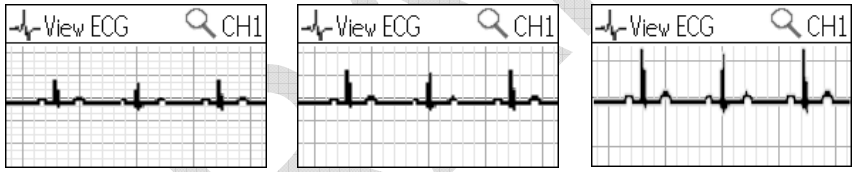
3. **Checking ECG signals:**

   Using the left and right arrow buttons, select View ECG (icon) and press the Enter button.

   You can change to another channel by pressing the left or right buttons. If any channel is not available due to an error detecting a lead, a "Lead Error" message will be displayed for only that affected channels. If the cable becomes disconnected, all channels will display "No Cable".

   To enter or exit zoom mode, press the left and right buttons simultaneously for one second. A magnifying glass ( ) will appear next to the channel number in the upper right corner. Pressing the right button will increase the amplitude of the signal, while pressing left will decrease the amplitude of the signal. Pacer pulse marks are displayed with a paced signal below the trace to indicate each detection of a pacer pulse.

   - Note that the gain setting only changes the display and not the gain of the ECG signal stored in the recorder.



.5x gain **1x gain (default)** **2x gain**

Grid background indicates the display gain.

Press the Enter button to return to the Setup Menu.

General notes:

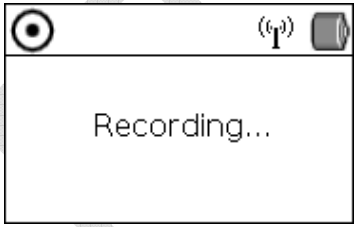
A. All button presses should beep to provide feedback for the user.
B. The backlight for the display is on while accessing the menus, after recording a manual event, or after receiving a text message.
C. The backlight will remain off during normal recording
D. Lead loss and Pacer detection is on all the time.
E. The number of channels a patient cable contains will determine the number of channels the recorder will record.

F. Although the device detection algorithms are very sophisticated, there is no guarantee that the device will catch all episodes of arrhythmia.

Start the Recording and Check Connection to Server

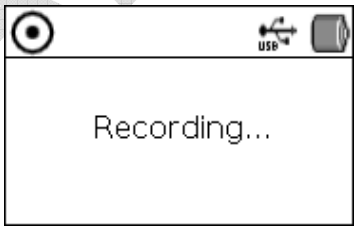
The Recording screen should now be displayed. An icon in the upper right corner indicates the type of connection that is being used to transfer the information to the Fusion Server.

(not transmitting)



Cellular

Bluetooth modem



USB cable

A majority of the time the recorder will not be transmitting an so there will only be the battery icon in the upper right corner.

Call the service center and verify the SN of the recorder has contacted the Fusion Server. It is now the job of the service center complete enrollment of the patient with the recorder.

Patient Operating Instructions

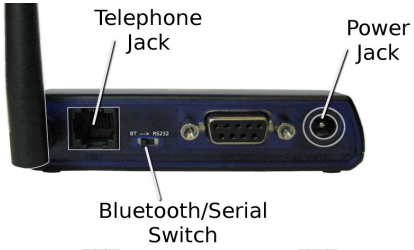
Establishing the Home Link

In accordance with FDA directive, Fusion Wireless Monitoring with patient alarm conditions requires the establishment of a Home Link alternative to cellular data communications. The Fusion recorder kit contains Bluetooth wireless hardware that must be connected to a normal RJ-11C telephone jack. The jack used should typically be located on the nightstand or near where the patient will spend most of their time during the procedure. Patients inside the home location should be in Home Link wireless contact if they are within approximately 75 feet of the system. Note: This modem has an actual line of site range of 328 feet but due to walls and other structural impedance the modem should be placed within 100 feet.

The Fusion recorder and Home Link modem connections are preset at the factory and do not need any user configuration.

Home Link hardware overview:

Bluetooth modem (top view)



Bluetooth modem (back view)

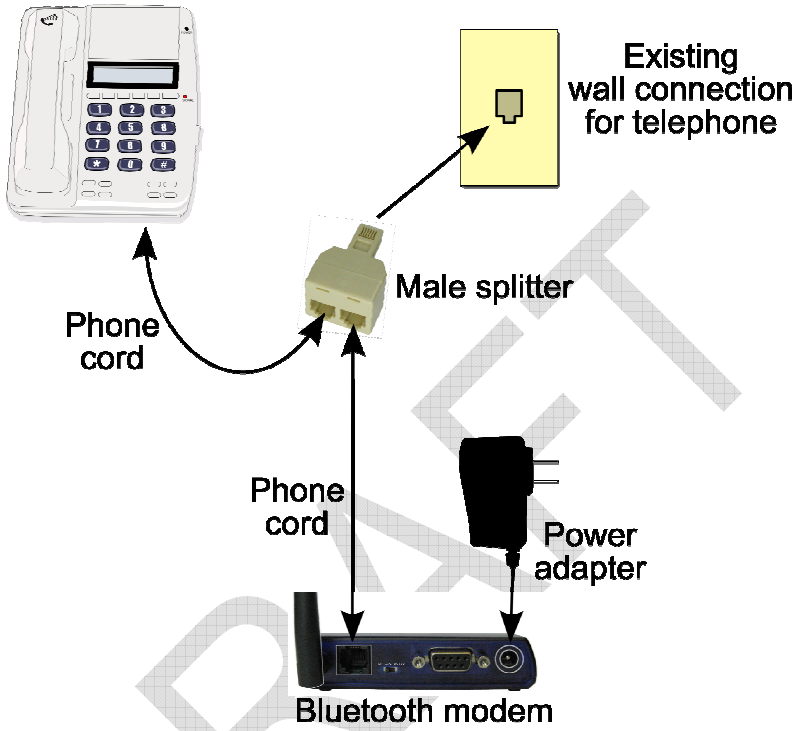
Telephone cord

Bluetooth modem power adapter

Male phone splitter

Female phone splitter

Installation of the Home Link modem:



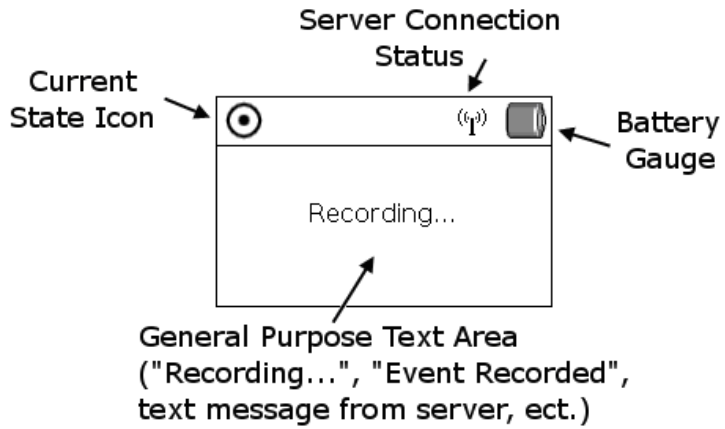
After installation of the Home Link, the patient must call the monitoring center to verify that the redundant data transfer system is able to communicate with the Fusion Server.

1. The PWR light should turn on when the modem has power.
2. The LINK light will turn on when the Fusion recorder connects to the modem.
3. The OH light will turn on when the telephone line is “Off Hook” meaning the modem has started a connection over the telephone line.
4. The ACT, TX, and RX lights will blink while the Fusion recorder is transmitting data.

Recorder information:

The recorder should be ready when you receive it from the technician. If there are any problems, refer to the Troubleshooting section.

Display overview:



To Hookup:

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 recorder.
4. The recorder is now recording data as seen in the above screenshot.
5. Insert the recorder into the holster and clip holster to belt or similar clothing.

Record ECG: ECG to be marked will be described by the physician.

1. Press the RECORD/ENTER button until an audible tone is heard, then release.
2. Hold as still as possible during recording but continue breathing. The recording should only last a few seconds.

Automatic Recording:

If an event is detected, the recorder will silently record and transmit the event to the monitoring center for further review.

Note about TEXT Messaging:

The Fusion Wireless Monitoring System Software can provide text messaging back the Fusion recorder. Messages up to 3 lines with 32 characters per line can be displayed on the LCD of the Fusion recorder to allow communications back to the patient. A TEXT message received by a recorder will initiate an audible alert of three beeps in rapid succession. The alert will repeat every 10 minutes until the patient presses one the arrow keys or is silenced by the monitoring center. The message shall be displayed continuously until cleared by the monitoring center. The patient is not able to clear the message unless the batteries are removed.

To Send:

In most cases, events are automatically downloaded to the receiving center via digital cellular link. If an appropriate cellular signal is not present for the transmission to start, the recorder will automatically connect to the Home Link Bluetooth modem. There isn't any patient interaction required for this transmission to occur.

Battery Change:

Remove cable

Open door

Pull ribbon

Check for blank screen

Insert new battery watching for correct polarity

Close door.

Troubleshooting (page 1 of 2)

Symptom	Recommended Solution
No display	Ensure batteries are inserted with correct polarity.
Will not record	Ensure RECORD button has been pressed.
	Ensure Patient Cable is inserted completely.
recorder stops recording	
Enter button pushed but a recording does not start	Patient cable must be inserted with a good connection to patient before an event recording starts.
Recorder will not turn off after removing batteries	The recorder will remain on for a few seconds after the battery is removed. Wait at least 5 seconds after removing the batteries to completely turn off the recorder. Verify screen is blank before replacing batteries.
Bluetooth connection does not allow dial out	Check the BT -> RS232 switch on the back of the Bluetooth modem. It should be set to "BT"

Troubleshooting (page 2 of 2)

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.
Rising tone	Ready to record

Service and Maintenance

Cleaning

Cleaning should occur before each patient use and more frequently if needed.

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 holster.

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 recorder, review the problem descriptions and solutions listed on the next page. If additional assistance is required contact customer support via phone, Fax or E-mail listed below. Call customer support before returning a recorder to make shipping arrangements.

A. Note there isn't any preventative inspection or maintenance that can be performed by the end user.

Service Items and Accessories

Note: Only authorized accessories are permitted.

Description	Part Number
Patient Cable, 3 channel, 5 lead	350-0302-00
Patient Cable, 2 channel, 4 lead	350-0302-01
Patient Cable, 1 channel, 3 lead	350-0302-02
Patient Cable, 1 channel, 2 lead	350-0302-03
Patient Cable, 2 channel, 3 lead	350-0302-04
Recorder belt clip / Holster	100-1910-001
Operator manual	600-0645-00
AA Lithium Battery Pack	350-0294-00
USB 2.0 Data Cable	200-2792-001
Phone splitter-Male	200-2899-001
Phone splitter-Female	200-2900-001
Phone cord, 6ft, RJ-11	200-2893-001
Bluetooth modem	350-0308-00

Equipment Symbols

Symbol	Description
	Type B Applied Part
	Consult manual
SN	Serial Number
CE 0086	Complies with the Medical Device Directive of the European Union.
	Waste Electrical and Electronic Equipment (WEEE) It is the responsibility of the end user to dispose of this equipment at a designated collection point for recycling.
	Date of Manufacture
Bluetooth™	Bluetooth trademark indicating conformity to specifications

Manufacturer:
Braemar, Inc.
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Contact Braemar for further technical information.

Authorized European Rep:
QNET BV
EC REP
Hommerterweg 286
6436 AM Amstenrade
The Netherlands

Specifications

Functional

Fusion	1, 2, or 3 channel
Sample rate	256 samples per second
User interface	LCD display and sound

Memory

Max total record time	
One channel	30 days
Two channel	30 days
Three channel	20 days
Type	Flash
Data retention	Non-volatile

Physical

Dimensions	4.1"x 2.25"x .75"
Weight with batteries	5.5 oz.
Enclosure	Molded plastic
Operating position	Any orientation

Electrical

Input impedance	10M min.
CMR ratio	60dB
AC signal range	+/- 5mV
DC signal range	+/- 300mV
Resolution	12 bits
Frequency response	.05Hz to 80Hz
FCC ID	HHMFUSIONMCT
IC ID	9158A-FUSION

Environmental

Operating temperature	0°C to +45°C
Non-operating temperature	-20°C to +65°C
Operating humidity	10% to 95% without condensation
Non-Operating humidity	5% to 95% without condensation

Battery

Type	(2) AA Lithium Thionyl
Life	Battery life varies greatly due to local wireless coverage, distance to the wireless towers, Bluetooth usage, number of arrhythmia detections and other factors. Typical life is approximately 8-10 days.
	Remove batteries during storage For optimum shelf life store batteries at ambient room temperature and 30% to 50% relative humidity

Warranty

12 months from shipment

Electromagnetic Emissions

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Class B	Fusion 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% without condensation.
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.

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: 

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.

Recommended Separation Distances

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

Fusion is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of Fusion can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Fusion 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 metres (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.

NOTE1: 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.

FCC / IC Statements

NOTICE: *This device complies with Part 15 of the FCC Operation is subject to the following two conditions:*

(1) this device may not cause harmful interference, and

(2) this device must accept any interference received, including interference that may cause undesired operation.

NOTICE:

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

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 0.522W/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.

Radio Frequency radiation exposure Information

For body worn operation, this device has been tested and meets the FCC RF exposure guidelines when worn in the belt clip / holster and used with the Braemar accessories supplied or designated for this product.
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.

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