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MEDIANA
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Medical Device

MEDIANA

Ultrasound Doppler System

OPERATOR MANUAL

F10

Table of Contents

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Section 1. Safety

1.1 Safe Operation

- Examine the monitor and any accessories periodically to ensure that the cables, line cords, transducers, and instruments do not have visible evidence of damage that may affect patient safety or monitoring performance. The recommended inspection terval is once per week or less. Do not use the F10 if there is any isible sign of damage.

- Do not attempt to service th F10. Only qualified service person should attempt any needed internal servicing.

- Perform periodic safety testing to insure proper patient safety. This should include leakage current measurement and insulation testing. The commended testing interval is once per year.

- The F10 is not specified or intended for operation in conjunction with any other type of monitoring equipment except the specific devices that have been identified for use in this Operator's Manual.

1.2 Warings

WARNING : Be informed that it may cause serious injury or death to the patient, property damage, material losses against the “Warning” sign.

WARNING : EXPLOSION HAZARD - Do not use the F10 in a flammable atmosphere where concentrations of flammable anesthetics or other materials may ocuur.

1.3 Cautions

CAUTION : Be informed that it may cause no harm in life but lead to injury against the “Caution” sign.

CAUTION : The relevant law restricts this device to sale by or on the order of a physician.

CAUTION : Keep the operating environment free of dust, vibrations, corrosive, or flammable materials, and extremes of temperature and humidity. The unit should be kept clean and free of transducer gel and other substances.

CAUTION : Do not operate the unit if it is damp or wet because of condensation or spills. Avoid using the equipment immediately after moving it from a cold environment to a warm, humid location.

CAUTION

- The equipment conforms to Class A according to IEC/EN 60601-1(Safety of Electric Medical Equipment)
- This equipment conforms to Level B according to IEC/EN 60601-1-2(Electromagnetic Compatibility Requirements)

CAUTION : Equipment containing primary batteries shall contain a warning to remove these batteries if Equipment is not likely to be used for some time.

Section 2. F10

2.1 F10

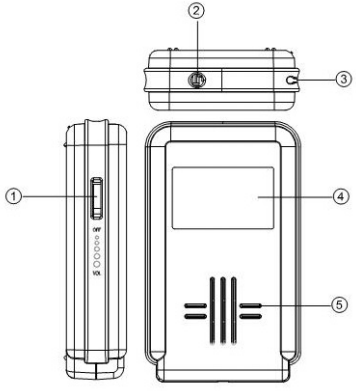
F10 is a pocket-sized fetal doppler that measures the fetal heart rate and outputs the fetal heart sound through a built-in speaker. Measuring the fetal heart rate(FHR) gives an indication of fetal well-being.

2.2 Configuration

- F10 Main Body (1EA)
- Carrying Case (1EA)
- User Manual (1EA)
- Ultrasound Gel (1EA)
- 1.5V Battery (2EA)

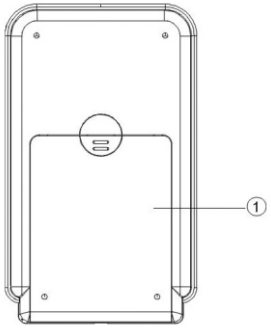
2.3 Composition

▶ Main Body (Front, Top and Left side View)



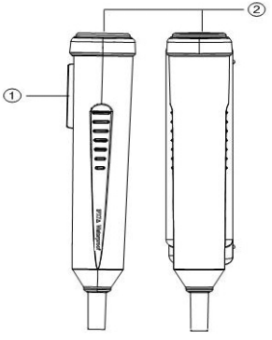
① Power and Volume Switch
② Ear Phone Jack
③ Probe Holder
④ LCD Window
⑤ Speaker

▶ Main Body (Rear View)



① Battery Cover

▶ Waterproof Probe (IPX7)



① Groove Joint
② Sensor

Section 3. How to use your F10 ?

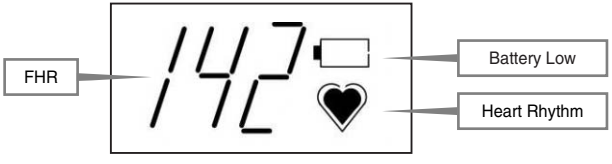
3.1 Operational Requirements

- F10 has to be used under surrounding temperature of 10℃ ~ 40 ℃ and humidity of 30% ~ 8%.
- Handle with care.
- Avoid dust or flammable materials.
- Make sure the batteries are inserted correctly.
- When detaching the probe from the main body, slide the probe upwards to prevent damage.

3.2 How to use ?

- Turn the power and volume switch counterclockwise to turn the device on and adjust the volume level.
- Apply a liberal amount of ultrasound gel to the face of transducer (end of the probe).
- Place the transducer directly against the abdomen, just above the point where the pelvic bones meet (in early pregnancy).
- Search for the fetal heart by slowly moving the probe around until the fetal heart sounds are heard.
- Search for the position which can get the clearest heart sound.
- When the input signal is good and stable, FHR will appear the screen and heart rhythm indicator will flash as shown in figure.

F10 Ultrasound Doppler System



- When the input signal is not stable, outer shape of heart rhythm indicator will flicker.
- If the voltage level of battery is lower than the required level, the battery low message “bat Lo” will appear as shown in Figure. In this case, the unit will not functional correctly and the batteries should be replaced.
- If the user wants to use external speaker, connect the audio cable with audio connection on top of the F10

3.3 Simple Clinic Information

- Acceleration : The pattern restored after FHR increasing more than 15 bpm for more than 15 sec. from baseline. (Baseline : FHR value in the section of no pains)
- Deceleration : The pattern restored after FHR decreasing more than 15 bpm for more than 15 sec. from baseline.
- Normal FHR : The pattern that FHR is formed between 120 and 160.
- Reactive : The case that Acceleration happens more than 2 times for 10 minutes. (Healthy)
- Non-Reactive : The case that Acceleration happens less than 2 times for 10 minutes.

Section 4. Maintenance and Cleaning

To keep the device clean, apply alcohol on a soft cloth and wipe the body and the probe once a month. Do not use lacquer, thinner, ethylene, or an oxidizing agent. If you use material that is not approved, it may cause damage to the product. In this case, the product will not be guaranteed within the warranty period. Keep the probes clean from dust or grime. Wipe the cable with a damp, and with clinical alcohol once a week. Do not immerse the main body or the probe in any liquid or detergent. Keep the main unit and the probe away from any liquid.

General Information

- F10 is classified as listed below;
  - Type-BF.
  - Internal powered equipment according to IEC/EN 60601-1
  - This equipment conforms to Level B according to IEC/EN 60601-1-2
- Turn the power off after use. If you do not turn the power switch off, 1 minute later, the sound will be muted automatically. In this case, a single “beep” sound will be heard. 5 minutes later, the system will go to sleep mode. In this case two “beep” sounds will be heard. The display will be turned off. In this mode power very little power is consumed.If you want to wake up the device from sleep mode, first of all, turn the power off and then 1 second later turn the switch on by turning the switch counterclockwise.
- 1.5V × 2(AA Type) Batteries are used for the system power. Do not use any other type of battery. Use of the wrong battery type may damage the equipment.
- Federal law restricts this device to sale by or on the order of a physician.
- Do not open the device cover or disassemble the device. Refer servicing to qualified personnel of Mediana Co., Ltd.
- Definition of Symbols

This symbol identifies a safety note. Be sure to understand the function of this control before using it. Control function is described in the operation manual(IEC60601-1)

Type BF Equipment(IEC60601-1)

IPX7 : 1meter of water for up to 30minutes(IEC60529)

Product Guarantee

Model Name : F10
Approval No. :
Approval Date :
Serial No. :
Warranty Period : 1 Year
Date of Purchase :
Customer Hospital :
Address :
Name :
Telephone :
Sales Agency :
Manufacturer : Mediana Co., Ltd.

※ Thank you for purchasing F10.
※ This product is manufactured and has passed through strict quality control and inspection.
※ Compensation standard concerning repair, replacement, refund of the product complies with “Consumer protection law”

Specifications

▶ Specifications

- Ultrasound Center Frequency : 2MHz
- Intensity : <10mW/cm2
- Sensitivity : 10~12 Weeks Onward
- Heart Rate Counting Range : 50~240bpm
- FHR Accuracy : ±2% of range
- Battery Type : 1.5V×2(LR6 battery / AA Type)
- Power consumption : 3VA, maximum
- Battery Life : About 360min (Continuously use)
- PC Interface : Sound Card (using by BCM220 S/W)
- Waterproof Probe : IPX7

▶ Physical

- Main Body : (L)75㎜×128㎜×(D)26㎜
- Probe : (L)25㎜×(H)131㎜×(D)25㎜
- Weight(Main Body and Probe) : 200g (with batteries)

▶ Environmental

- Operating Temperature : 10℃(50℉) to 40℃(104℉)
- Operating Humidity : 30% ~ 85% non-condensing
- Operating Atmospheric Pressure : 70㎪ ~ 106㎪
- Storage Temperature : -10℃(14℉) to 60℃(131℉)
- Storage Humidity : 20% ~ 95% non-condensing
- Storage Atmospheric Pressure : 70㎪ ~ 106㎪

F10 Operator manual Rev.00

Specifications

▶ Acoustic Ouput Terms and Definitions

Term	Definition
$I_{SPTA.3}$	Derated spatial peak, temporal average intensity in units of milliwatts/cm^2.
TI type	Applicable thermal index for the transducer, imaging mode, and exam type.
TI value	Thermal index value for the transducer, imaging mode, and exam type.
MI	Mechanical index.
$I_{pa.3}$@MImax	Derated pulse average intensity at the maximum MI in units of W/cm^2.
TIS	(Soft tissue thermal index) is a thermal index related to soft tissues. TIS scan is the soft tissue thermal index in an auto-scanning mode. TIS non-scan is the soft tissue thermal index in the non-autoscanning mode.
TIB	(Bone thermal index) is a thermal index for applications in which the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of bone. TIB non-scan is the bone thermal index in the non-autoscanning mode.
TIC	(Cranial bone thermal index) is the thermal index for applications in which the ultrasound beam passes through bone near the beam entrance into the body.
A_{aprt}	Area of the active aperture measured in cm^2.
$P_{r.3}$	Derated peak rarefactional pressure associated with the transmit pattern giving rise to the value reported under MI (Megapascals).
Wo	Ultrasonic power, except for TIS_{scan}, in which case it is the ultrasonic power passing through a one centimeter window in units of milliwatts.
$W_{.3}(z_1)$	Derated ultrasonic power at axial distance z_1 in units of milliwatts.
$I_{SPTA.3}(z_1)$	Derated spatial-peak temporal-average intensity at axial distance z_1 (milliwatts per square centimeter).
z_1	Axial distance corresponding to the location of maximum [min($W_{.3}(z)$, $I_{TA.3}(z)$ x 1 cm^2)], where z > zbp in centimeters.
z_{bp}	$1.69\sqrt{A_{aprt}}$ in centimeters.
z_{sp}	For MI, it is the axial distance at which $p_{r.3}$ is measured. For TIB, it is the axial distance at which TIB is a global maximum (for example, $z_{sp} = z_{b.3}$) in centimeters.
$d_{eq}(z)$	Equivalent beam diameter as a function of axial distance z, and is equal to $\sqrt{(4/(\pi))((W_0)/(I_{TA}(z)))}$, where ITA(z) is the temporal-average intensity as a function of z in centimeters.
fc	Center frequency in MHz.
Dim. of A_{aprt}	Active aperture dimensions for the azimuthal (x) and elevational (y) planes in centimeters.
PD	Pulse duration (microseconds) associated with the transmit pattern giving rise to the reported value of MI.
PRF	Pulse repetition frequency associated with the transmit pattern giving rise to the reported value of MI in Hertz.
p_r@PII_{max}	Peak rarefactional pressure at the point where the free-field, spatial-peak pulse intensity integral is a maximum in Megapascals.
d_{eq}@PII_{max}	Equivalent beam diameter at the point where the free-field, spatial-peak pulse intensity integral is a maximum in centimeters.
FL	Focal length, or azimuthal (x) and elevational (y) lengths, if different measured in centimeters.

Specifications

▶ Acoustic Ouput Table

This table indicates the acoustic output for the systzem and transducer combinations with a thermal index or mechanical index equal to or greater than one. This table is organized by transducer model and imaging mode.

Transducer Model: F10 (Operating Mode: CW Doppler)

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					A_{aprt} 1	A_{aprt}>1		
Global Maximum Index Value			(a)	—	(a)	—	0.727	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	0.00236					
	W_0	(mW)		—	#		6	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	1.4				1.4	
	$d_{eq}(z_{sp})$	(cm)					1.414	
	f_c	(MHz)	2.00	—	#	—	2.00	#
	Dim of A_{aprt}	X (cm)		—	#	—	0.898	#
		Y (cm)		—	#	—	0.65	#
Other Information	PD	(μsec)	10					
	PRF	(Hz)	99968					
	p_r@PII_{max}	(MPa)	#					
	d_{eq}@PII_{max}	(cm)						
	Focal Length	FL_x (cm)		—	#	—		#
		FL_y (cm)		—	#	—		#
	$I_{PA.3}$@MI_{max}	(W/cm^2)	#					
Operating Control Conditions	Control 1: Exam Type							
	Control 2: Sample Volume							
	Control 3: PRF							
	Control 4: Sample Volume Position							

(a) This index is not required for this operating mode; value is <1.
(b) This transducer is not intended for transcranial or neonatal cephalic uses.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)
" Data are not applicable for this transducer/mode.

Specifications

▶ Compliance

Item	Compliant with
Classification	Internally powered
Type of protection	Type BF – Applied part
Mode of operation	Short-time operation
Degree of protection	Class IPX7 (DOP Probe)
General	93/42/EEC Directives for medical devices
	ISO9001:2000 Quality Management Systems - Requirements
	ISO13485:2003 Quality Systems– Medical Devices –Particular requirements for the application of ISO9001
	ISO14971:2000+A1:2003 Risk analysis managements – medical devices
	IEC60601-1:1988+A1:1991+A2:1995 General requirements for Safety and Essential Performance
	IEC60601-1-1:2000 Safety requirements for medical electrical systems
	ISO10993-1:2003 Biological evaluation of medical devices – Part 1: Evaluation and testing
Electrocardiograph	IEC60601-2-37:2005 Particular requirements for the safety of electrocardiographic monitoring equipment
	BS EN 61266:1995, IEC 61266:1994 Ultrasonics. Hand-held probe Doppler foetal heartbeat detectors. Performance requirements and methods of measurement and reporting
	BS EN 61157:2007 Standard means for the reporting of the acoustic output of medical diagnostic ultrasonic equipment
Electromagnetic Compatibility	IEC 60601-1, sub clause 36, IEC/ IEC60601-1-2:2001+A1:2004 Electromagnetic compatibility-requirements & test
	IEC61000-4-2:2001 Electrostatic Discharge Ed 1.2
	IEC61000-4-3:2006 Radiated RF electromagnetic field Ed 2.1
	IEC61000-4-8:2001 Power frequency (50/60Hz) magnetic field Ed 1.1
	CISPR 11 (EN55011) RF Emissions Group 1, Class B
Labeling	EN1041:1998 Information supplied by the manufacturer with medical devices
Marking	IEC /TR60878:2003 Graphical symbols for electrical equipment in medical practice
	EN980:2003 Graphical symbols for use in the labeling of medical devices
	ISO7000:2004 Graphical symbols for use on equipment-index and synopsis

Manufacture's Declaration

WARNING : For best product performance and measurement accuracy, use only accessories supplied or recommended by Mediana. Use accessories according to the manufacturer's directions for use and your facility's standards. The use of accessories, transducers, and cables other than those specified may result in increased emission and/or decreased immunity of the FM20.

The F10 is intended for use in the electromagnetic environment specified below. The customer or user of the F10 should assure that it is used in such an environment.

1. Guidance and manufacturer's declaration - Electromagnetic Emissions

Emission Test	Compliance	Electromagnetic Environment-guidance
RF emission CISPR 11	Group 1	The F10 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	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emission IEC 61000-3-3	Complies	

2. Guidance and manufacturer's declaration - Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
The F10 is intended for use in the electromagnetic environment specified below. The customer or the user of the F10 should assure that it is used in such an environment.			
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electric fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial and/or hospital environment
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial and/or hospital environment

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Voltage dips, short interruptions and voltage variations on power supply IEC 61000-4-11	<5 % U T (>95 % dip in UT) for 0.5 cycle 40 % U T (60 % dip in UT) for 5 cycles 70 % U T (30 % dip in UT) for 25 cycles <5 % U T (95 % dip in UT) for 5 sec.	<5 % U T (>95 % dip in U T) for 0.5 cycle 40 % U T (60 % dip in U T) for 5 cycles 70 % U T (30 % dip in UT) for 25 cycles <5 % U T (95 % dip in UT) for 5 sec.	Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the F10 image intensifier requires continued operation during power mains interruption, it is recommended that the F10 image intensifier be powered from an uninterruptible power supply or a battery.
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	It may be necessary to position the F10 further from the sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

3. Guidance and manufacturer's declaration - Electromagnetic Immunity

Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic environment guidance
The F10 is intended for use in the electromagnetic environment specified below. The customer or the user of the F10 should assure that it is used in such an environment.			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the FM20, including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. **Recommend separation distance**
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 800 MHz 3 V/m 800 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz 3 V/m	$d = [3,5 / V_1]\sqrt{p}$ $d = [3,5 / E_1]\sqrt{p}$ 80 MHz to 800 MHz $d = [7 / E_1]\sqrt{p}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to he transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters as deter-mined by an electromagnetic site survey,[a] should

Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic environment guidance
			be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with he following symbol: 
Note: At 80 MHz and 800 MHz, the higher frequency range applies. Note: 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 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 F10 is used exceeds the applicable RF compliance level above, the F10 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the FM20. [b] Over the frequency range 150 kHz to 80MHz, field strengths should be less than $[V_1]$ V/m			

4. Recommended separation distances between portable and mobile RF communications equipment and the FM20

Recommended separation distance between portable and mobile RF communications equipment and the FM20			
The F10 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of he F10 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the F10 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 [m]**		
	150 kHz to MHz $d = [3,5 / V_1]\sqrt{p}$	***80 MHz to 800 MHz*** $d = [3,5 / E_1]\sqrt{p}$	***800 MHz to 2.5GHz*** $d = [7 / E_1]\sqrt{p}$
0.01	0.12	0.11	0.23
0.1	0.37	0.36	0.73
1	1.17	1.16	2.33
10	3.69	3.68	7.37
100	11.66	11.66	23.33
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: At 80MHz and 800MHz, the separation distance for the higher frequency range applies Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

5. Immunity and Compliance Level

Immunity Test	IEC 60601 Test Level	Actual Immunity Level	Compliance Level
Conducted RF IEC 61000-4-6	150 kHz to 80 MHz	3 Vrms	3 Vrms
Radiated RF IEC 61000-4-3	80 MHz to 2.5 GHz	3 V / m	3 V / m

6. Guidance and manufacturer's declaration - Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
The F10 is intended for use in the electromagnetic environment specified below. The customer or the user of the F10 should assure that it is used in such an environment.			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	The F10 must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that enters the shielded location with a minimum RF shielding effectiveness and, for each cable that enters the shielded location
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 800 MHz 3 V/m 800 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz 3 V/m	Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than 3 V / m.[a] Interference may occur in the vicinity of equipment marked with he following symbol: 
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. Note: It is essential that the actual shielding effectiveness and filter attenuation of the shielded location be verified to assure that they meet the minimum specification.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile 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 F10 is used exceeds 3V / m, the F10 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the F10 or using a shielded location with a higher RF shielding effectiveness and filter attenuation.			