



January 2010 Amendments to FSA 4.0 User Manual 6th Edition (April 2009)

Note the following amendments to FSA 4.0 User Manual 6th Edition (April 2009); the amendments indicated will be incorporated into the next FSA user manual release.

Page 3/76 (Title page 2) add:

Federal Communications Commission (FCC) statement

The Federal Communications Commission (in 47 CFR 15.105) has specified that the following notice be brought to the attention of the users of this product.

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense. The end user of this product should be aware that any changes or modifications made to this equipment without the approval of Vista Medical could result in the product not meeting the Class A limits, in which case the FCC could void the user's authority to operate the equipment.

Page 9 Section 1.2.5 Cleaning the FSA Mat add:

Isolation bags are intended for single use only; dispose of them according to your institution's biological waste disposal guidelines.

Page 10 Section 1.2.6 Proper Care of the FSA Interface Modules add:

-The Type 4 Interface Module operates on 9V DC or battery power. To protect against possible damage to the interface module, use only the Vista Medical supplied power supply provided with the system, **refer to safety notices indicated below.**

-Disconnect the battery pack from the module if not in use for an extended period.

-If module function stops during use, reset the module by disconnecting then reconnecting the power source from the device.

It is the operator's responsibility to ensure all cables are in good condition; inspect all cables for nicks or abrasions prior to each use.

To clean, disconnect the module from the power supply. Wipe the exterior of the interface module with a soft cloth dampened with water. Do not use liquid or aerosol cleaners which may contain flammable substances.

Also see Safety Notices: CAN/CSA C22.2 601.1-M90, UL 60601-1 and EN60601-1, Electronic Emissions Notices (pages to follow)

New Section Safety Notices, add:

CAN/CSA C22.2 601.1-M90, UL 60601-1 and EN60601-1

This product has been tested and found to comply with CAN/CSA C22.2 601.1-M90, UL 60601-1 and EN60601-1. The following information is provided for clarification:

- Medical Device Type: Class I with measurement function
- Degree of protection against electric shock: Type B Applied Part
- Degree of protection against ingress of water: IPX0

- Degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide: Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
- Mode of operation: Continuous
- Environmental Operating Conditions: 10-40°C, 30-75% rH non-condensing, 700-1060hPa

Electronic Emissions Notices

Federal Communications Commission (FCC) statement

The Federal Communications Commission (in 47 CFR 15.105) has specified that the following notice be brought to the attention of the users of this product.

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense. The end user of this product should be aware that any changes or modifications made to this equipment without the approval of Vista Medical could result in the product not meeting the Class A limits, in which case the FCC could void the user's authority to operate the equipment. This device complies with Part 15 of the FCC Rules. 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.

Industry Canada compliance statement

This Class A digital apparatus complies with Canadian ICES-003.

Cet appareil numérique de la classe A est conforme à la norme NMB-003 du Canada

IEC 60601-1-2:2004 (Ed 2.1)

This product has been tested and found to comply to IEC 60601-1-2:2004 (Ed 2.1) for electromagnetic compatibility (EMC) as a Class A product. The tests performed and test levels are listed in the accompanying tables. The user, operator or installer of this equipment is advised of the following:

1. In a domestic environment this product may cause radio interference in which case the user may be required to take adequate corrective measures.
2. Portable and mobile RF communications can affect medical electrical equipment.
3. This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures such as:
 - Reorienting or relocating the receiving antenna.
 - Increasing the separation between the equipment and the receiver.
 - Connecting 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.

4 **WARNING:** Use of this equipment with accessories or cables other than those qualified and sold by Vista Medical may result in increased emissions or decreased immunity of this equipment and may cause the system to be non-compliant with the requirements of IEC 60601-1-2:2004 (Ed 2.1).

5. This equipment should not be stacked or used adjacent to other equipment. If stacked or adjacent use is necessary, the equipment should be observed to verify normal operation in the configuration in which it is used.

6. External equipment, i.e. personal computer, intended for connection to signal input, signal output or other connectors, shall comply with relevant EN standard (e.g. EN 60950 for IT equipment and the EN 60601 series for Medical electrical equipment). In addition, all such combinations, medical equipment intended to be connected to the other equipment – systems - shall comply with the standard EN 60601-1-1, Safety requirements for medical electrical systems.

Equipment not complying with EN 60601 shall be kept outside the patient environment, as defined in the standard. ¹

Any person who connects external equipment to signal input, signal output or other connectors has formed a system and is therefore responsible for the system to comply with the requirements of EN 60601-1-1. If in doubt, contact qualified technician or your local representative.

¹ The normal distance of at least 1.5 m from the patient or the patient support shall be provided.

The FSA product has been certified to comply with 93/42/EEC for the purposes of CE Marking as a Medical Device.

Table 201 Requirements

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.			
Emissions test	Compliance	Electromagnetic environment – guidance	
RF emissions CISPR 11	Group 1	The equipment 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 A	The equipment is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the equipment or shielding the location.	
Harmonic emissions IEC 61000-3-2	Class A		
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies		

Table 202 Requirements

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the Equipment should assure that it is used in such an environment.			
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 with documented necessary	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical 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 ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 UT = 230 Vac	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles No anomalies 95% dip meets requirements.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50 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.

Table 204 Requirements


The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	1 Vrms ^a	<p>Portable and mobile RF communications equipment should be used no closer to any part of the equipment including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3,5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>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 meters (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</p> <p>Interference may occur in the vicinity of known RF transmitting devices and equipment marked with the following symbol:</p> 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	
NOTE 1 At 80 MHz and 800 MHz, 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.			
<p>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 equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the equipment</p> <p>b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.</p>			

Table 206 Requirements














Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT			
<p>The EQUIPMENT is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the EQUIPMENT can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EQUIPMENT as recommended below, according to the maximum output power of the communications equipment.</p>			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $D = 3.5 \sqrt{P}$	80 MHz to 800 MHz $D = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $D = 2.3 \sqrt{P}$
0.01	0.35	0.12	0.23
0.1	1.1	0.38	0.73
1	3.5	1.2	2.3
10	11	3.8	7.3
100	35	12	23
<p>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.</p> <p>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

New Section: Approved Parts and Accessories, add:

Part#	Description	Other
LI2	Interface Module Type 4 9V DC 500 mA	
LI20	Interface Module Type 5 5V DC 250 mA (via USB)	
LI24	Interface Module Wireless Type 5	
ACC2010	European (Schuko) Cord Set, 8'/2.5m	Max. length 10'/3m
ACC3010	UK Cord Set, 8'/2.5m	Max. length 10'/3m
ACC3015	North American Cord Set, Medical Grade, 10'/3m	Max. length 10'/3m
ACC8015	Danish Cord Set, Medical Grade, 8'/2.5m	Max. length 10'/3m
ACC2021	Interface Power Supply, 9V Universal Medical Grade Power Supply Model# WM10-9V Input: 100-240VAC, 50-60Hz, 0.4A/Output: 9VDC/1000mA Output Connector: 5.5x2.1x12mm Approvals: CSA 22.2 No. 601, UL60601, TUV EN60601, CE Mark (LVD) alternate: 2 - Model# GTM21097-1509 Input: 90 to 264VAC, 47-63 Hz, 1.6 A /Output: 9VDC/1.7A Output Connector: 5.5x2.1x12mm Approvals: UL 60601.1, CUL TO 22.2 NO. 601.1, TUV TO EN60601.1, PSE TO J60950, CB Report	Manufactured by: 1 - PowDec Technologies 7013 Realm Drive Suite E San Jose CA 95119 USA 2 - GlobTek Inc. 186 Veterans Drive Northvale NJ USA 07647
FSA1050	Battery Pack 9V	Manufactured by: Priority Electronics Ltd. 55 Trottier Bay Winnipeg MB Canada R3T 3R3
FSA1055	Wireless Type 5 Battery Pack	Manufactured by: Priority Electronics Ltd. 55 Trottier Bay Winnipeg MB Canada R3T 3R3
FSA1060	9V Battery	
LI3	6'/1.8m FSA Serial Cable type 4	Max. length 10'/3m
LI5	6'/1.8m Serial Extension Cable	Max. length 10'/3m
LI8	4'/1.2m InShoe/Custom Extension Cable, black	Max. length 10'/3m
LI62	6'/1.8m USB Cable (with ferrites)	Max. length 10'/3m
ACC018	Type 5 Wireless Kit: 1 - LI24 Interface Module Type 5 (Wireless) 1 - LI141 SD1000 Bluetooth Serial Adaptor with 1 dBi stub antenna 1 - LI142 UD100 Bluetooth USB Adaptor with 1 dBi stub antenna 1 - L13C - 9"/23cm Parani Cable (Type 5) 1 - FSA1056 - 9V Battery Pack and Battery 1 - Instructions <i>Also includes 1 - LI62 1.8m/6' USB Cable (with ferrites) for wired use</i>	
ACC9011	Type 4 Wireless Kit: 1 - LI141 SD1000 Bluetooth Serial Adaptor with 1 dBi stub antenna 1 - LI142 UD100 Bluetooth USB Adaptor with 1 dBi stub antenna 1 - LI121 - 12"/30cm Parani Cable (Type 4) 1 - FSA1056 - 9V Battery Pack and Battery 1 - Instructions	

WARNING: Use of this equipment with accessories or cables other than those qualified and sold by Vista Medical may result in increased emissions or decreased immunity of this equipment and may cause the system to be non-compliant with the requirements of IEC 60601-1-2:2004 (Ed 2.1).

New Section: Definition of Symbols, add:

	Alternating current
	Direct current
	Type B applied part
	Caution risk of danger or attention, consult accompanying document
	Date of manufacture
	Manufactured by
	Serial number
	Model number
	EC representative
	Electrostatic sensitive device
	Keep dry
	Do not dispose of with other waste products; contact your distributor or the manufacturer for instructions.
	Type 4 Module - Start or Stop recording mode Type 5 Module - User input required as instructed in manual.

New Section Product Environmental Specifications, add:

Temperature:	Operating: 10 to 40°C Storage: -40 to +70°C
Relative Humidity:	Operating: 30 to 75% RH (non-condensing) Storage: 10 to 100% RH (non-condensing)
Atmospheric pressure:	Operating: 700 to 1060 hPa Storage: 500 to 1060 hPa

Other Notes:

As of November 1 2009, shipments of FSA no longer include:

- FSA Manual Trigger Cable #FSA1040 (discontinued and no longer available). Referenced in sections 2.1, 2.2, 4.2
- FSA 6' Serial Cable #L13; (available on request). Referenced in sections 2.1, 3.3 and throughout.
- FSA Serial Port Extension #LI5; (available on request). Referenced in sections 2.1, 3.3 and throughout.
- Hard Copy FSA User's Manual; (available on request). An electronic version will be available on your FSA Software CD and at our website for no charge; the same information is also available through the software menu selection **Help-FSA4 Help**.

**Please watch our website for software and manual updates. Go to:
www.pressuremapping.com, Techsupport, FSA & VeV Downloads or
<http://www.pressuremapping.com/index.cfm?pageID=31>**