

Appendix 1 Product Specifications

A1.1 Environmental Specifications

Working	Temperature:	+5 °C ~ + 40 °C (+41 °F ~ +104 °F)
	Relative Humidity:	25% ~ 80% (non-condensing)
	Atmospheric Pressure:	860hPa ~ 1060hPa
Transport and Storage	Temperature:	-20 °C ~ +55 °C (-4°F ~ +131 °F)
	Relative Humidity:	25% ~ 93% (non-condensing)
	Atmospheric Pressure:	700hPa ~ 1060hPa

A1.2 Physical Specifications

Monitor		
Dimensions and Weight	Size (depth x width x height) :	350mm x 300mm x 104mm
	Weight:	Approx. 3.5 kg
Power Supply	Operating Voltage:	100V-240V~
	Operating Frequency:	50Hz/60Hz
	Input Power :	70VA
	Battery:	14.8V/4200mAh 14.8V/2100mAh
Standards Compliance	IEC/EN 60601-1, IEC/EN 61157, IEC/EN 60601-2-37, IEC/EN 60601-1-2	
Anti-electric Shock Type		Class I equipment with internal power supply
Anti-electric Shock Degree		FHR1, FHR2, TOCO, FM, FS BF
		IUP BF
		DECG CF
Degree of Protection against Harmful Ingress of Water for the Transducers		IPX 8
Degree of Safety in Presence of Flammable Gases		Equipment not suitable for use in presence of flammable gases
Disinfection/Sterilizing Method		Refer to this user manual for details
EMC		Group 1 Class A
Working System		Continuous running equipment

Earth Leakage Current (Limit)		N.C. 500μA	S.F.C. 1000μA
Enclosure Leakage Current (Limit)		N.C. 100μA	S.F.C. 500μA
Patient Leakage Current (Limit)		N.C. d.c. 10μA a.c. 10μA	S.F.C. 50μA 50μA
Patient Auxiliary Current (Limit)		N.C. d.c. 10μA a.c. 10μA	S.F.C. 50μA 50μA
Display	LCD Size:	5.6”	
	Active Area:	112.9 mm (W) x 84.7 mm(H)	
	Resolution:	640 (RGB) x 480	
	Display Mode	Normally White, Transmissive	
Signal Interface	DB9, RJ45 network interface		
Ultrasound Transducer			
Weight:		190g	
Cable Length:		2.5m	
Dimension:		88mm×35mm	
TOCO Transducer			
Weight:		180g	
Cable Length:		2.5m	
Dimension:		88mm×35mm	
Remote Event Marker			
Length:		2.5m	
Weight:		56g	

A1.3 Performance Specifications

Ultrasound	Technique:	Ultrasound Pulse Doppler with autocorrelation
	Pulse Repetition Rate:	2 KHz
	Pulse Duration:	92 μs
	Ultrasound Frequency:	(1.0±10%) MHz

Ultrasound	p- <1 MPa	
	$I_{ob} < 10 \text{ mW/cm}^2$	
	$I_{spta} < 100 \text{ mW/cm}^2$	
	FHR Measurement Range:	50 bpm ~ 240 bpm
	Resolution:	1 bpm
	Accuracy:	$\pm 2 \text{ bpm}$
	Dielectric Strength:	> 4000Vrms
	ISATA@ the transducer face: 1.865 mW/cm^2	
	Entrance beam: 6.08 cm^2	
	Measurement uncertainties for ISATA: $\pm 26.6\%$	
	Measurement uncertainties for ultrasonic power: $\pm 26.6\%$	
DECG	Technique:	Peak-peak detection technique
	DFHR Measurement Range:	30bpm ~ 240bpm
	Resolution:	1bpm
	Accuracy:	$\pm 1 \text{ bpm}$
	Input Impedance:	> 10M (Differential, DC50/60Hz)
	Input Impedance:	> 20M (Common Mode)
	CMRR:	> 110dB
	Noise:	< $4\mu\text{Vp}$
	Skin Voltage Tolerance:	$\pm 500 \text{ mV}$
	Fetal Input Voltage Current:	$20\mu\text{Vp} \sim 3 \text{ mVp}$
TOCO	TOCO Range:	0% ~ 100%,
	Non-linear Error:	$\pm 10\%$
	Resolution:	1%
	Zero Mode:	Automatic/ Manual
	Dielectric Strength:	> 4000Vrms
IUP	Pressure Range:	0 mmHg ~ 100 mmHg
	Sensitivity:	$5\mu\text{V/V/mmHg}$
	Non-linear Error:	$\pm 3 \text{ mmHg}$
	Resolution:	1%
	Zero Mode:	Automatic / Manual

AFM	Technique:	Pulsed Doppler ultrasound
	Range:	0% ~ 100%,
	Resolution:	1%
Marking	Manual fetal movement mark	

A1.4 Recorder Specifications

Paper:	Z-fold, thermosensitive (compatible with GE and PHILIPS recorder paper)
Paper width:	152mm (GE), 150mm (PHILIPS)
Effective printing width:	110mm (American Standard) 120mm (International Standard)
FHR printout width:	70mm (American Standard) 80mm (International Standard)
FHR scaling:	30bpm/cm (American Standard) 20bpm/cm (International Standard)
TOCO printout width:	40mm
TOCO scaling:	25%/cm
Printing speed:	
Standard Speed (Real-Time Traces):	1 cm/min, 2 cm/min, 3 cm/min
Fast Print Speed (Stored Traces):	Up to 15mm/sec
Accuracy of data:	± 5% (X axis)
Accuracy of data:	± 1% (Y axis)
Resolution:	8 dots/mm
Record Information:	FHR1 trace/mark, FHR2 trace/mark, TOCO trace, AFM trace, fetal movement mark, event mark, AUTO-zero symbol, date, time, printing speed, ID, name, FHR2 Offset etc.

A1.5 Lithium-ion Battery Specifications

Specification \ Battery	01.21.064143	01.21.064142
Nominal Capacity	4200mAh	2100mAh
Charge Current (Standard)	0.2C ₅ A(1200mA)	0.28C ₅ A (600mA)
Working Time	2~5 hours (depending on configuration)	2~5 hours (depending on configuration)
Nominal Voltage	14.8V	
Charge Voltage (Standard)	(16.8±0.1) V	
Cycle Life	≥300 times	
Charge Temperature	0°C ~ +50°C (+32°F ~ +122°F)	
Operating Temperature	-20°C ~ +60°C (-4°F ~ +140°F)	
Relative Humidity	45% ~ 75%	
Charge Mode	Constant current/ constant voltage	
Storage	Short Term (within 1 month): -20 °C ~ +60 °C (-4 °F ~ +140 °F) Middle Term (within 3 months): -20 °C ~ +45 °C (-4 °F ~ +113 °F) Long Term (within 1 year): -20 °C ~ +20 °C (-4 °F ~ +68 °F) During storage, recharge the battery at least every six months.	
Charge State When Leaving Factory	20% ~ 50%	

A1.6 Low Output Summary Table

Low Output Summary Table

(for systems with no transducers having global maximum index values exceeding 1.0)

System: F2 Fetal Monitor

Transducer Model	I _{spta.3} (mW/cm ²)	TI Type	TI Value	MI	I _{pa.3@MI_{max}} (W/cm ²)
PW 1.0 MHz	2.77	TIS	0.055	0.029	0.01
		TIB	0.629		