F6, F6 Express

Fetal & Maternal Monitor

Version 1.0

Data Sheet

EDAN

Physical Specifications	Dimensions(D×W×H)	347mm×330mm×126mm
	Weight	F6 5.3kg approx. F6 Express 6.1kg approx.
	Display	10.1 inch 800×600 Pixel Multicolor LCD
	Signal Interface	RS232 Interface (DB9 or D-Sub) RJ45 Interface
	Ultrasound Transducer	8-Crystal Transducer Cable Length 2.5m Weight 190g Dimension 88mm × 35mm Color Pink
	TOCO Transducer	Cable Length 2.5m Weight 180g Dimension 88mm × 35mm
	Remote Event Marker	Cable Length 2.5m Weight 56g
	ECG	Cable Length 3m Weight 213g
	SpO2	Cable Length 2.4m Weight 68g
	NIBP	Cable Length 3.3m Weight 194g
	TEMP	Cable Length 3m Weight 55g
Power Supply	Mains Supply	Operating Voltage 100V ~ 240V~ Operating Frequency 50Hz/60Hz Input Power 1.0 ~ 0.5A
	Rechargeable Li-ion Battery	Nominal Voltage 14.8V Nominal Capacity 5000mAh Continuous Working Time >2 hours Necessary Charge Time <7 hours Cycle Life >300 times
Recording	Recorder	Thermal Dot-matrix Recorder
	Paper	Z-fold, Thermosensitive (Compatible with GE and Philips recorder papers)
	Paper Width	152mm/150mm
	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) 1/2/3 cm/min Fast Print Speed(Stored Traces) Up to 15mm/sec
	Accuracy of Data	± 5% (X-Axis) ± 1% (Y-Axis)
	Resolution	8 dots/mm
	Record Information	FHR1 trace/mark, FHR2 trace/mark, TOCO trace, AFM trace/black mark, fetal movement mark, event mark (and annotation), AUTO-zero symbol, alarm indicator, SOV alarm indicator, US1 and US2 signal loss alarm indicator, wired/wireless monitoring status mark, date, time, printing speed, ID, name, FHR2 Offset, HR, SpO2, SYS, DIA, MAP, PR, TEMP, CTG analysis results etc.
FHR	Operating Mode	PW with Autocorrelation
	Working Frequency	(1.0±10%)MHz
	FHR Measurement Range	50bpm ~ 240bpm
	Resolution	1bpm
	Accuracy	±2bpm
	Alarm	FHR Alarm
	Ultrasound Output	$I_{sppa.3}$<190W/cm^2 $I_{spta.3}$<94mW/cm^2 I_{sata}<20mW/cm^2 TI<1.0 MI<1.0
	Temperature Rise	When applied to the patient, the ultrasound transducer may warm slightly (less than 2°C (3.6°F) above ambient temperature). When NOT applied, at the ambient temperature of 40°C (104°F), the ultrasound transducer may reach the highest temperature of 43°C (109.4°F).
	Effective Radiating Area	(628 ± 15%)mm^2
	Dielectric Strength	4000Vrms
	Other Info.	p- <1MPa I_{ob} <10mW/cm^2 I_{spta} <100mW/cm^2 Max Output Power <15mW
TOCO	TOCO Range	0 ~ 100
	Non-linear Error	±10%
	Resolution	1
	Baseline Drift due to Temperature Changes	1 unit/min/°C (free air) 5 units/min/°C (underwater)
	Zero Mode	Automatic (TOCO value becomes zero or below lasting for 30 seconds)/Manual
	Dielectric Strength	>4000Vrms
DECG	DFHR Measurement Range	30bpm ~ 240bpm
	Resolution	1bpm

	Accuracy	±1bpm
	Alarm	DFHR Alarm
	Technique	Peak-peak detection technique
	Input Impedance	>10MΩ (Differential, DC50/60Hz) >20MΩ (Common Mode)
	CMRR	>110dB
	Noise	<4μVp
	Skin Voltage Tolerance	±500mV
	Fetal Input Voltage Current	20μVp ~ 3mVp
IUP	Pressure Range	0mmHg ~ 100mmHg (0.0kP ~ 13.3 kPa)
	Non-linear Error	±3mmHg (±0.4kPa)
	Resolution	1mmHg (0.1kPa)
	Sensitivity	5μV/V/mmHg
	Zero Mode	Manual
MFM & AFM	Display Range	0 ~ 999
	FM Mode	Automatic/Manual
	AFM Mode	Trace (default)/Black Mark
	AMF Technique	Pulsed Doppler Ultrasound
MECG	MHR Measurement Range	30bpm ~ 240bpm
	MHR Measuring Accuracy	±2bpm
	Resolution	1 bpm
	MHR Alarm Limits	30bpm ~ 240bpm
	Alarm	HR Alarm
	Anti-electric Shock Type	Defibrillating-proof
	Input Signal Range	±8 mV PP
	ECG Waveform	Manual control ECG waveform display
	ECG falls off	Detect Automatically
	Patient Leakage Current (Limit)	N.C. S.F.C. d.c. 10μA 50μA a.c. 10μA 50μA
	Patient Auxiliary Current (Limit)	N.C. S.F.C. d.c. 10μA 50μA a.c. 10μA 50μA
	Differential Input Impedance	>5MΩ
	Display Sensitivity	2.5mm/mV (×0.25), 5mm/mV (×0.5), 10mm/mV (×1), 20mm/mV (×2), AUTO gain
	Electrode Offset Potential Tolerance	±500mV
	Auxiliary Current (Leads off detection)	Active electrode <100nA Reference electrode: <900nA

	Accuracy and Response to Irregular Rhythm	According with ANSI/AAMI EC13-2002 Sect.4.1.2.1 e) The MHR value displays after a stable period of 20s: Ventricular bigeminy 80bpm±1bpm Slow alternating ventricular bigeminy 60bpm±1bpm Rapid alternating ventricular bigeminy 120bpm±1bpm Bidirectional systoles 91bpm±1bpm
	Bandwidth(-3dB)	Diagnosis 0.05 Hz ~ 150 Hz Monitor 0.5 Hz ~ 40 Hz
	Response time to Change in MHR	MHR range 80bpm ~ 120bpm Range 7s ~ 8s (average 7.5s) MHR range 80bpm ~ 40bpm Range 7s ~ 8s (average 7.5s)
	Tall T-wave Rejection	Exceeds ANSI/AAMI EC13-2002 Sect. 3.1.2.1 (C) minimum recommended 1.2mV T-Wave amplitude
SpO_2	Measurement Range	50% ~ 100%
	Resolution	1%
	Measuring Accuracy (EDAN)	90% ~ 100% ±2% 70% ~ 90% ±4% <70% unspecified
	Measuring Accuracy (Nellcor)	70% ~ 100% ±2% <70% unspecified
	Data update period (EDAN)	1s
	Data update period (Nellcor)	2s
	PR Measurement	Range 30 ~ 240bpm Resolution 1bpm Accuracy ±3bpm
	SpO_2 Alarm Limits	50% ~ 100%
	Alarm	PR Alarm and SpO_2 Alarm
	Wavelength	Red light (660±3)nm Infrared light (905±10)nm Emitted light energy <15mW
NIBP	Measurement	Systolic Pressure Diastolic Pressure Mean Artery Pressure
	Method	Oscillometric Method
	Measurement Range	Systolic Pressure 40mmHg ~ 270mmHg (5.3kPa ~ 36.0kPa) Diastolic Pressure 10mmHg ~ 215mmHg (1.3kPa ~ 28.7kPa) Mean Artery Pressure 20mmHg ~ 235mmHg (2.7kPa ~ 31.3kPa)
	Resolution	1mmHg (0.1kPa)
	Measuring Accuracy	Max. average deviation ≤±5mmHg (≤±0.8kPa) Max. standard deviation ≤8mmHg (≤1.2kPa)
	Measuring Time (Normal)	30 ~ 45s

	Measuring Time (MAX)	120s
	Alarm Limits	Systolic Pressure 40mmHg ~ 270mmHg (5.3kPa ~ 36.0kPa) Diastolic Pressure 10mmHg ~ 215mmHg (1.3kPa ~ 28.7kPa) Mean Artery Pressure 20mmHg ~ 235mmHg (2.7kPa ~ 31.3kPa)
	Alarm	Systolic Pressure Diastolic Pressure Mean Artery Pressure Alarm
	Software Over Voltage Protection	(297±3)mmHg [(39.6±0.4)kPa]
	Hardware Over Voltage Protection	(320±10)mmHg [(42.8±1.3)kPa]
	Cuff pressure measuring range	0mmHg ~ 300mmHg (0.0kPa ~ 40.0kPa)
TEMP	Channel	1
	Measurement Range	0°C ~ 50°C
	Resolution	0.1°C
	Accuracy	±0.3°C (Transducer error excluded ±0.1°C) (Transducer ≤ ±0.2°C)
	Unit	°C/°F
	Refresh Time	1 ~ 2s
	Self-Check	5 ~ 10min
	Alarm Limits	0.0°C ~ 50.0°C
	Alarm	TEMP Alarm
	Measuring Mode	Direct Mode
	Position	Axilla
Data Transmission	Data Export	Ethernet/USB
	Report Format	TRC
	Data Management System	MFM-CNS
	HIS connection	HL7/GDT
Safety Specifications	Standards Compliance	IEC 60601-1:2005, EN 60601-1:2006/AC:2010, IEC 60601-1-2:2007, EN 60601-1-2:2007/AC:2010, IEC/EN 60601-2-27, IEC/EN 60601-2-37, IEC/EN 60601-2-49, IEC 80601-2-30, ISO 80601-2-61, ISO 80601-2-56, EN 12470-4, AAMI/ANSI EC13
	Anti-electric Shock Type	Class I equipment with internal power supply
	Anti-electric Shock Degree	FHR1, FHR2, TOCO, FM, IUP — BF SpO2, NIBP — BF (Defibrillating-proof) DECG — CF

		ECG, TEMP CF (Defibrillating-proof)
	Degree of Protection against Harmful Ingress of Water	Main Unit IPX1, protected against vertically falling water drops (provided recorder drawer is shut and the monitor is not mounted on the wall vertically) US/TOCO Transducers IPX8, protected against the effects of continuous emersion in water
	Degree of Safety in Presence of Flammable Gases	Equipment not suitable for use in presence of flammable gases
	EMC	CISPR11 Group 1 Class A
	Working System	Continuous Operation
Environmental Specifications	Temperature	Working +5°C ~ +40°C (+41°F ~ +104°F) Transport and Storage -20°C ~ +55°C (-4°F ~ +131°F)
	Relative Humidity	Working 15% ~ 93% (non-condensing) Transport and Storage 15% ~ 93% (non-condensing)
	Atmospheric Pressure	Working 86kPa ~ 106kPa Transport and Storage 70kPa ~ 106kPa

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