

Appendix 1 Technical Specifications

A1.1 Safety Specifications

Comply with:	IEC 60601-1:2005/A1:2012 EN 60601-1:2006/A1:2013 IEC 60601-1-2:2007 EN 60601-1-2:2007/AC:2010 IEC/EN 60601-2-25	
Anti-electric-shock type:	Class II	
Anti-electric-shock degree:	Type CF with defibrillation-proof	
Degree of protection against harmful ingress of water:	Ordinary equipment (Sealed equipment without liquid proof)	
Disinfection/sterilization method:	Refer to the user manual for details (Please see Chapter 10, "Cleaning, Care and Maintenance")	
Degree of safety of application in the presence of flammable gas:	Equipment not suitable for use in the presence of flammable gas	
Working mode:	Continuous operation	
EMC:	CISPR 11, Group 1, Class A	
Patient Leakage Current:	NC	<10 μ A (AC) / <10 μ A (DC)
	SFC	<50 μ A (AC) / <50 μ A (DC)
Patient Auxiliary Current:	NC	<10 μ A (AC) / <10 μ A (DC)
	SFC	<50 μ A (AC) / <50 μ A (DC)

A1.2 Environment Specifications

	Transport & Storage	Working
Temperature:	DP12/DE15/DE18 ECG sampling box: -40°C (-8°F) ~ +55°C (+131°F)	+5°C (+41°F) ~ +40°C (+104°F)

	DX12 ECG sampling box: -20°C (-4°F)~+55°C (+131°F)	
Relative Humidity:	25%RH~93%RH Non-Condensing	25%RH~80%RH Non-Condensing
Atmospheric Pressure:	70 kPa ~106 kPa	86 kPa ~ 106 kPa

A1.3 Physical Specifications

Dimensions	DE18/DE15 ECG sampling box: 139mm× 96mm × 25mm, ± 5mm
	DP12 ECG sampling box: 148mm (L) ×100 mm (W) × 40mm (H) , ± 2mm
	DX12 transmitter: 63mm(L)×107mm(W) ×23mm(H), ± 2mm
	DX12 receiver: 155mm(L)×100mm(W)×30mm(H), ± 2mm
Weight	DE15/DE18 ECG sampling box: Approx. 215g
	DP12 ECG sampling box: Approx. 210g
	DX12 transmitter: Approx. 113g (not including battery)
	DX12 receiver: Approx. 173g

A1.4 Power Supply Specifications

Power Supply:	PC	Operating Voltage: 110V-240V~
		Operating Frequency: 50 Hz/60Hz
	DE18/DE15 ECG Sampling Box	DC 5V
		Input Power: 1 VA(MAX), 0.5 VA(MIN)
	DP12 ECG Sampling Box	5V, 1VA (MAX), 0.5VA (MIN)
	DX12 transmitter	Input Power: 2x1.5V Excell Alkaline AA IEC LR6; Operation life of battery ≥12 hours
	DX12 receiver	DC 5V
		Input Power: 350mW

A1.5 Performance Specifications

HR Recognition		
HR Range	30 bpm ~300 bpm	
Accuracy	±1 bpm	
ECG Sampling Box Performance		
Leads	DE18	18 leads
	DE15	16 leads
	DP12/DX12	12 leads
Acquisition Mode	DE18	simultaneously 18 leads
	DE15	simultaneously 16 leads
	DP12/DX12	simultaneously 12 leads
Sample Frequency	DE18/DE15	1kHz (Analysis) 16kHz (Sampling)
	DP12	1kHz (Analysis) 1kHz (Sampling)
	DX12	0.5kHz (Analysis) 10kHz (Sampling)
A/D	DE18/DE15/DP12	24 bits
	DX12	18bits
Resolution	DE18/DE15	0.1575uV/LSB
	DP12/ DX12	2.52uV/LSB
Input Voltage Range	<±5mVp-p	
Time Constant	≥3.2s	

CMRR	DE18/DE15		$\geq 123\text{dB}$ (AC OFF)
	DP12		$\geq 115\text{dB}$ (AC OFF)
	DX12		$\geq 100\text{dB}$ (AC OFF)
Frequency Response	DE18/DE15		0.01Hz~300Hz (-3dB)
	DP12/DX12		0.05Hz~150Hz (-3dB)
Gain	2.5, 5, 10, 20, 10/5, AGC (mm/mV)		
Input Impedance	DE18/DE15		$\geq 100\text{M}\Omega$
	DP12		$\geq 50\text{M}\Omega$
	DX12		$\geq 20\text{M}\Omega$
Input Circuit Current	DP12/DE15/DE18		$\leq 10\text{nA}$
	DX12		$\leq 0.05\mu\text{A}$
Calibration Voltage	$1\text{mV} \pm 2\%$		
DC Offset Voltage	DE18/DE15/DP12		$\pm 600\text{mV}$
	DX12		$\pm 500\text{mV}$
Minimum Amplitude:	$20\mu\text{Vp-p}$		
Noise	DE18/DE15/DP12		$\leq 12.5\mu\text{Vp-p}$
	DX12		$\leq 15\mu\text{Vp-p}$
Recovery Time After Defibrillation	$< 5\text{ s}$		
Multichannel crosstalk	$\leq 0.5\text{mm}$		
Patient Leakage Current:	NC	$< 10\mu\text{A}$ (AC) / $< 10\mu\text{A}$ (DC)	
	SFC	$< 50\mu\text{A}$ (AC) / $< 50\mu\text{A}$ (DC)	
Patient Auxiliary Current:	NC	$< 10\mu\text{A}$ (AC) / $< 10\mu\text{A}$ (DC)	
	SFC	$< 50\mu\text{A}$ (AC) / $< 50\mu\text{A}$ (DC)	

Insulation		4000Vrms/min	
Filter	AC	DE18/DE15/DX12	50Hz/60Hz/Off
	EMG	DE18/DE15/ DX12	25Hz/35Hz/45Hz/Off
	DFT	DX12	0.05Hz/0.32Hz/0.67Hz
		DE18/DE15	0.01Hz/0.05Hz/0.32Hz/0.67Hz
	LOWPASS Filter	DX12	150Hz/100Hz/75Hz
		DE18/DE15	300Hz/270Hz/150Hz/100Hz /150Hz/100Hz/75Hz
Pacemaker Detection		DE18/DE15	±750uV ~ ±700mV, 50us ~ 2.0ms
		DP12	±2mV ~ ±700mV, 0.1ms ~ 2.0ms
		DX12	±2mV ~ ±500mV, 0.1ms ~ 2.0ms
DX12 Bluetooth			
Transmitting Frequency		2402 Hz ~ 2480Hz	
Frequency Band		2402 Hz ~ 2480Hz	
Modulation Type		FHSS, GFSK, DPSK, DQPSK	
Transmitting Power		≥ 0 dBm	

NOTE: Operation of the equipment below the minimum amplitude may cause inaccurate results.