T	echnical Specification
Enclosure	
Weight	258grams (9.1 ounces) with batteries
Dimensions	13.5cm × 7.5cm × 2.8cm
Alarms	
Categories	Patient status and system status
Notification	Audible and visual
Setting	Full storage, low battery and sensor off
-	Pulse rate (30-350bpm), SpO2 (0-100%)
Range Alarm volume level	0-85dB
	U-65UB
Range, Accuracy and Resolution	B V.
Range Type	Range Values
Measurement Ranges	
SpO2 measuring range	0-100%
Pulse rate range	30-350bpm
Measurement Accuracy	
SpO2 measuring accuracy	70-100% (±2%), <70% undefined
Pulse rate measuring accuracy	±2bpm/±2% take maximum
Resolution	
SpO2	1%
Pulse rate	1bpm
Electrical	
AC power requirement	100-240VA, 47-63Hz
Power comsumption	20VA
Batteries	
Types	Alkaline/Ni-Mh Batteries, IEC: LR6
Operating time	≥20hours
Charge time	≤ 6hours
Environment	2 Officials
	0-45℃
Operating tempearture	
Storage temperature	-20-60°C
Operating humidity	30-95%
Operating altitude	-500-5000m
Trends	
Types	Tabular
Memory	Save total 120 hours data events. Save data and time, alarm conditions, pulse rate and SpO2 measurements
Standards and Certification	
IEC 62366	Medical devices-Application of usability engineering to medical devices
IEC 62304	
	Medical device-software life cycle processes
MDD 93/42/EEC	European Medical Device Directive
ISO 13485	Medical equipment-Quality management system
EN ISO 14971	Medical devices-Risk management
EN 60601-1	Medical electrical equipment
EN 60601-2	Medical electrical equipment
	Medical electrical equipment
EN 60601-8	· ····································
EN 60601-8 EN 980	Symbols for use in labeling of medical devices
	Symbols for use in labeling of medical devices Information supplied by the manufacture of medical devices
EN 980 EN 1041	Symbols for use in labeling of medical devices Information supplied by the manufacture of medical devices Medical electrical equipment-Particular requirements
EN 980 EN 1041 ISO 80601-2-61	Symbols for use in labeling of medical devices Information supplied by the manufacture of medical devices Medical electrical equipment-Particular requirements for the basic safety and essential performance of pulse
EN 980 EN 1041 ISO 80601-2-61	Symbols for use in labeling of medical devices Information supplied by the manufacture of medical devices Medical electrical equipment-Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use
EN 980 EN 1041 ISO 80601-2-61 EN ISO 10993-1 EN ISO 10993-5	Symbols for use in labeling of medical devices Information supplied by the manufacture of medical devices Medical electrical equipment-Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use Biological evaluation of medical devices Biological evaluation of medical devices
EN 980 EN 1041 ISO 80601-2-61 EN ISO 10993-1 EN ISO 10993-5 EN ISO 10993-10	Symbols for use in labeling of medical devices Information supplied by the manufacture of medical devices Medical electrical equipment-Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use Biological evaluation of medical devices Biological evaluation of medical devices Biological evaluation of medical devices
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