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ECG-Based PICC Tip Confirmation System

12.3

This device is certified by Underwriters Laboratories, Control Number E468297, to comply with General Medical Equipment requirements for Electrical Shock, Fire and Mechanical Hazards only, in accordance with ANSI/AAMI ES60601-1 AMD 1 (2012), CAN/CSA-C22.2 No. 60601-1 (2014).



12.4

This device has no essential performance as intended by IEC60601-1 AM1.

Table 1

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The C3 Wave System is intended for use in the electromagnetic environment specified below. The customer or the user of the C3 Wave System should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1	The C3 Wave System 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 C3 Wave System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

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