

### Overview of Regulatory Agencies

Safety Mark	Agency	Categories	Country
UL	UL	Safety – Listed	USA
UC	UL	Safety – Classified	USA
cUC	UL	Safety – Classified	Canada
UR	UL	Safety – Recognized	USA
cUL	UL	Safety – Listed	Canada
cUR	UL	Safety – Recognized	Canada
FCC Home or Office Use	FCC – DoC <sup>1</sup>	RF Emissions <sup>2</sup> : Class B (home) Class A (office)	USA
IC	IC – DoC <sup>1</sup>	RF Emissions <sup>2</sup> : Class B or A	Canada
GS	TÜV	Safety Ergonomics	Germany
Bauart	TÜV	Safety	Germany
CE	EU – DoC <sup>1</sup>	Safety EMC RF Emissions <sup>2</sup> : Class B or A Immunity	European Union
VCCI	VCCI	RF Emissions <sup>2</sup> : Class B or A	Japan
C-Tick	SMA	RF Emissions <sup>2</sup> : Class B or A	Australia New Zealand
TCO99	TCO	Safety Emissions <sup>2</sup> Immunity Ergonomics Energy Savings Ecology	Sweden
DHHS 21CFR	FDA	X-Ray – CRT only	USA
MPRII	MPR – DoC <sup>1</sup>	X-Ray – CRT only	Sweden
AR/S	UL de Argentina	Safety	Argentina

<sup>1</sup> DoC – Declaration of Conformity issued by Elo stating compliance with named standards.

<sup>2</sup> Radio Frequency (RF) Emissions Class B or A – Most Elo models meet the more strict Class B requirements.

**Notes:**

UL 2601-1 is entitled "Medical Electrical Equipment - Part 1: General Requirements For Safety." It is a standard written by Underwriters Laboratories (UL) harmonized to the international standard IEC 60601-1 with the same title.

The cUL mark is Underwriters Laboratory's mark indicating compliance with Canadian product safety standards.

CSA 22.2 No. 601-1 is entitled "Medical Electrical Equipment - Part 1: General Requirements For Safety." This standard is written by Canadian Standards Association (CSA) and is harmonized to the international standard IEC 60601-1 with the same title.

CSA vs. UL....Both agencies are accredited and have reciprocal agreements for the acceptance of test results. Therefore both marks indicate compliance with Canadian product safety standards. The advantage of UL is the ability to obtain U.S. and Canadian compliance with one submittal.

Class A vs. B.....Equipment used in commercial settings is considered Class "A". Class "B" digital devices are those intended for use in the home. FCC limits for RF radiation differ depending on the application of the digital device. The test distances for RF radiation are approximately three times closer for Class "B" than Class "A".

A CB Scheme is the international system for acceptance of test reports dealing with the safety of electrical and electronic products. It is a multilateral agreement among participating countries and certification organizations. A manufacturer utilizing a CB test report issued by one of these organizations can obtain national certification in all other member countries of the CB Scheme. The Scheme is based on the use of international (IEC) Standards. If some members' national standards are not yet completely harmonized with IEC Standards, national differences are permitted if clearly declared to all other members. The CB Scheme utilizes CB Test Certificates to attest that product samples have successfully passed the appropriate tests and are in compliance with the requirements of the relevant IEC Standard and with the declared national differences of various member countries.