



TELUS iDOC

CSA Standards Approvals

Each iDOC® – interactive Doctor On Call – system has been individually inspected by CSA International Certified Engineers to the current medical, electrical, and safety standards in use as follows:

Approvals

All components and system approved to:

- **CSA C22.2 #0-M1991** “General Requirements – Canadian Electrical Code, Part II”
- **CSA C22.2 #0.4-M1982** “Bonding and Grounding of Electrical Equipment”
- **CSA C22.2 #125-M1984** “Electromedical Equipment”
- **CSA C22.2 #950-M1995** “Safety of Information Technology Equipment, Including Electrical Business Equipment”
- **SPE-1000-99** “Model Code for the Field Evaluation of Electrical Equipment”

These documents cannot be detailed here or reproduced in any part, but may be purchased from the CSA Web site at:

www.csa-intl.org/onlinestore/GetCatalogDrillDown.asp?Parent=0

Risk classification

Medical devices are classified according to their risk to patients.

There are three classes:

- **Class I.** These devices present minimal potential for harm to the user and are often simpler in design than Class II or Class III devices. Examples include enema kits and elastic bandages.
- **Class II.** Most medical devices are considered Class II devices. Examples of Class II devices include powered wheelchairs and some pregnancy test kits.
- **Class III.** These devices usually sustain or support life, are implanted, or present potential unreasonable risk of illness or injury. Examples of Class III devices include implantable pacemakers and breast implants.

The iDOC is a Class I medical device, as is the Tandberg Intern II. Both are suitable for external (non-invasive) casual patient contact.

Other standards

- **UL2601-1** is an umbrella standard used in the United States by UL for general purpose medical use
- **CSA 601.1** is an almost identical standard used in Canada to UL2601-1
- **EMC 601.1** is an almost identical standard used in Europe to UL2601-1

Some competitors have certified their telehealth video conferencing systems for sale globally, which requires further standards support pertinent to the regions of sale. Standards required are UL2601.1, CSA 601.1, and EMC 601.1, and bear the ULc, and EMC labels.

Since the iDOC is restricted for sale only in Canada, international approval to UL or EMC standards is not required to be certified for Risk Class I Medical use. Therefore CSA has certified to the standards most appropriate for Canadian health care use, namely CSA C22.2 #0, #0.4, #125, and #950, as well as SPE- 1000-99, under the general provincial guidelines as indicated above

CSA 601.1 is a one-time approval for a manufactured system. CSA 601.1 approval can be obtained only for fixed product configurations. Changes to or the addition of electrical parts to a medical cart system, such as scopes, etc. not covered under certification are not allowed, and will void any CSA approvals if power is supplied by the medical cart. Since the iDOC is certified every time a medical cart is built, peripherals such as scopes etc. powered by the cart become part of the assembly, with the totality being certified. This gives the iDOC flexibility in configuration: customer choice of video conference system, multiple LCD screens, wireless Ethernet, and medical peripherals may be added per order, with the assurance that all systems plugged together will have CSA medical approval.

For verification that CSA has examined your iDOC, look for the CSA label on the rear panel. Corroborating paperwork with the CSA Engineer’s signature may be provided at your request.