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IEC/TR 80002-1:2009 provides guidance for risk assessment as per ISO 14971:2007. It does not add to or change the requirements of ISO 14971:2007 or IEC 62304:2006. IEC/TR 80002-1:2009 aims at risk management practitioners who perform risk management when software is included in medical device or system.

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IEC 80002-1, which is a technical report, has been prepared by a joint working group of subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice, and ISO technical committee 210: Quality management and corresponding general aspects for medical devices.

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Published: 2009-11-06. Date of approval: 2009-10-29. International relationships : IEC TR 80002-1:2009 IDT. ICS: 35.240.80 - IT applications in health care technology Item number: M237209

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