

Chiller Requirements

The Coolix 4000 chiller is in agreement with the following standards:

- CSA C22.2 No. 601 (this includes UL 60601-1 & IEC 60601-1 applied for medical devices)
- EMC/EMI compliance to IEC 60601-2
- EHS: non-ozone depleting substance, CFC free and non-forbidden products.
- CE marking certifying compliance with EMC and LVD directives and applicable standards.

LYTRON[™]
Total Thermal Solutions[™]

DECLARATION OF CONFORMITY

Product Description: Liquid Recirculating Chiller (Coolix 4000)

Model Number: RC7141G4, RC7141G5, RC7141G7, & RC7141G8

We, Lytron Incorporated, 55 Dragon Court, Woburn, Massachusetts, 01801, USA, declare that the product described above is in conformity with Low voltage Directive 73/23/EEC – European Union (EU) & EMC Directive 89/336/EEC – European Union (EU) using the relevant sections of the following standards and other normative documents:

CENELEC EN 60601-1

Medical Electrical Equipment Part 1: General Requirements for Safety Incorporates Corrigendum July 1994; Includes Amendments A1: 1993, A11: 1993, A12: 1993, A2: 1995, and A13: 1996; IEC 601-1: 1988 + A1: 1991 + A2: 1995 + Corrigendum 1995, Modified

CENELEC EN 60601-1-2-2001

Medical Electrical Equipment Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests IEC 60601-1-2:2001

This product has been qualified in accordance with the requirements established in Low Voltage Directive 73/23/EEC and EMC Directive 89/336/EEC and is manufactured in compliance with Lytron's registered EN ISO 9001:2000; BS EN ISO 9001:2000; ANSI/ASQ Q9001:2000 Quality System.


Authorized Lytron Representative

9/3/08
Date

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F4.3.32 Rev C 09/03/08

