



TECHNICAL NOTE

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SeeDOS Ltd
cwalters@seedos.com

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SUBJECT: CDX-2000B Electrometer

The following information is provided as a service to our users and customers:

The purpose of this memo is to outline the reasons that additional testing to IEC601-1, IEC601-1-2, IEC601-4 and IEC60731 is not required for the Standard Imaging CDX-2000B Electrometer. These reasons include the following:

- The CDX-2000B electrometer is a single, high range version of the dual range MAX 4000 electrometer. In this capacity it is substantially equivalent to the MAX 4000 and the PREMIER 3000 electrometer, which is a single, low range version of the MAX 4000. The MAX 4000 was certified to IEC601-1 IEC601-1-2 by ETL/ITS. The MAX 4000 and PREMIER 3000 are both currently CE-MDD marked.
- The hardware differences between the CDX-2000B and the MAX 4000 are limited to removal of the range switching relay, and the changing of a resistor value and a capacitor value in the front end amplifier to produce the desired range and response time. None of these changes have any effect on internal oscillators, battery charging or RS-232 communications circuits.
- The hazard analysis and essential requirements checklist are substantially equivalent between the CDX-2000B and the MAX 4000.
- IEC60731 for dosimeters with ionization chambers used in radiotherapy is a system standard and is not easily applied to distinct components of a system. The CDX-2000B, like the PREMIER 3000 and the MAX 4000 are not provided as part of a system. Rather, they are designed to be used with a wide variety of ion and well chambers, from Standard Imaging, as well as other manufacturers. Nonetheless, the CDX-2000B, as well as the PREMIER 3000 and MAX 4000 complies with the applicable sections of this standard and in particular the requirements of IEC 601-1 and IEC 601-1-2.
- The changes in firmware between the CDX-2000B, Premier 3000 and MAX-4000 are not significant and are controlled through the Product Development Process and Change Notice system.

Therefore, it is concluded that no additional IEC601-1-2 testing is required for the CDX-2000B, the MAX 4000 testing is applicable and that this outline fulfills the Technical File requirements for EMC/EMI.

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