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Australian/New Zealand Standard

Radiotherapy simulators

Part 2: Guidelines for functional performance characteristics

[IEC title: Radiotherapy simulators—Guidelines for functional performance characteristics]



AS/NZS 4213.2:1994

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee on Medical Diagnostic Imaging Equipment, HT/23, as a joint Standard under the terms of the Active Cooperation Agreement between Standards Australia and Standards New Zealand.

This Standard is identical with and has been reproduced from IEC 1170:1993, *Radiotherapy simulators—Guidelines for functional performance characteristics*.

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AUSTRALIAN/NEW ZEALAND STANDARD

Radiotherapy simulators**Part 2:
Guidelines for functional performance characteristics****1 Introduction**

The guidelines given in this report are recommendations both to MANUFACTURERS and to USERS. They provide guidance to MANUFACTURERS on the needs of radiotherapists in respect of the performance of RADIOTHERAPY SIMULATORS and they provide guidance to USERS wishing to check the MANUFACTURER'S declared performance characteristics, to carry out acceptance tests and to check periodically the performance throughout the life of the EQUIPMENT.

IEC 601-1* is a general standard for the safety of medical electrical EQUIPMENT. It is supplemented by IEC 1168**, a standard which lays down particular requirements for RADIOTHERAPY SIMULATORS. It has been issued as a disclosure standard. It is a standard which standardizes methods of declaring the RADIOTHERAPY SIMULATOR functional performance characteristics. It standardizes the TYPE TEST conditions and TYPE TEST methods to which MANUFACTURERS' declared values of functional performance relate.

A format for the presentation of functional performance values is contained in IEC 1168 as annex A. It is repeated herein in 2.1, with the addition of a set of suggested values which reflect the need for precision in RADIOTHERAPY and the knowledge of what is reliably achievable technically. A corresponding rationale for the suggested values is presented in 2.2.

In order to check whether each individual EQUIPMENT at the time of installation performs in a manner consistent with the set of functional performance values declared by the MANUFACTURER based upon his TYPE TEST data, it is customary to perform a series of acceptance tests at the USER's site before the EQUIPMENT is put into full medical use. Because of the limitations of time and test equipment, this series of acceptance tests is usually less extensive than the TYPE TESTS specified in the disclosure standard, IEC 1168.

During the working life of the RADIOTHERAPY SIMULATOR, periodic tests are usually conducted by the USER to check whether the functional performance of the EQUIPMENT is satisfactory. Because the available EQUIPMENT time is limited, a highly abbreviated set of test conditions is essential. Individual tests should not be repeated any more or less frequently than can be justified by experience with the particular EQUIPMENT or EQUIPMENT type. Suggested periodic tests to be performed during the working life of the RADIOTHERAPY SIMULATOR and suggested intervals between such tests are presented in 4.1. The MANUFACTURER may recommend different intervals or additional or different tests, depending on the special requirements of the RADIOTHERAPY SIMULATOR in question.

* IEC 601-1. 1988, *Medical electrical equipment – Part 1: General requirements for safety*, and Amendment 1, 1991.

** IEC 1168: 1993, *Radiotherapy simulators – Functional performance characteristics*

2 General, TYPE TESTS

2.1 *Format of annex A of the disclosure standard with suggested functional performance values (in brackets)*

2.1.1 *Introduction*

The purpose of 2.1 is to provide a suggested format for the presentation of functional performance values corresponding to the standardized statements of functional performance in the disclosure standard, IEC 1168.

USERS of RADIOTHERAPY SIMULATORS may find this format useful in getting information from the MANUFACTURERS on the expected performance, in recording acceptance test values measured at the time of installation and in periodic testing of performance during the working life of the EQUIPMENT.

MANUFACTURERS may find it useful in declaring the functional performance values for their particular types of RADIOTHERAPY SIMULATORS in response to IEC 1168.

It is not suggested that a MANUFACTURER should provide information to USERS from his TYPE TEST in any greater detail than a simple declaration of these functional performance values.

As a result of extensive deliberation by Working Group 1 of IEC sub-committee 62C, a set of suggested values of functional performance was agreed upon with respect to the standardized statements of IEC 1168.

Values are designated +/- where they represent permissible deviations in more than one direction from a desired point or value. The +/- designation is not used where the tolerance represents permissible deviation in any one direction between two points or values. The abbreviations "max." and "min." are used for "maximum" and "minimum", respectively.