GOSSEN METRAWATT CAMILLE BAUER GMC-Instruments

TESTING OF MEDICAL DEVICES

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APPLICATION NOTE

INTRODUCTION

Service providers who operate electrical medical devices must assure that they're safe for users and patients. Assuring safe operation includes subjecting such devices to necessary testing in accordance with the current state-of-the-art. As of May 2007, IEC 62353 has been added to the scope of required testing in a uniform fashion around the world.

This new standard is based on VDE 0751 which has been valid in Germany and Austria for many years, into which changes embodied in IEC 62353 have since been incorporated.

WHICH DEVICES ARE TESTED PER VDE 0751 / IEC 62353?

The standard applies only to the testing of electrical medical devices or systems, as well as components included in such devices or systems, which comply with IEC 60601-1.

The range of applications for devices manufactured in accordance with IEC 60601-1 grows immensely each year. One need only consider the rapidly growing fitness and wellness sectors. Nearly all devices offered in these areas have to be tested in accordance with VDE 0751.

All devices located in close proximity to patients (see figure 1) must also be tested in accordance with VDE 0751.

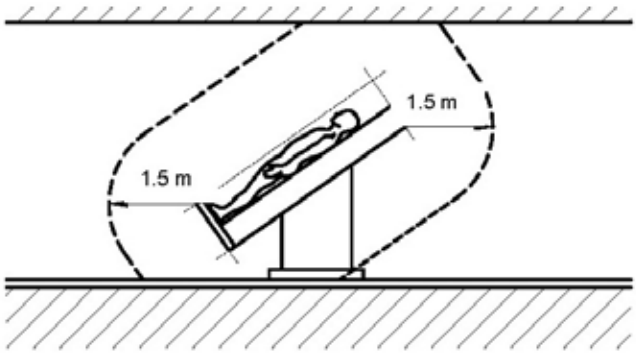
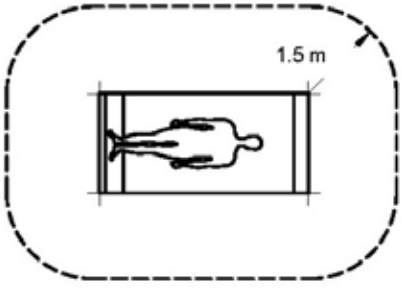


Figure 1: Patient Environment



The standard also allows for the testing of devices which are not manufactured in accordance with IEC 60601-1, thus expanding the range of applications to devices which would otherwise be tested per VDE 0701/0702 as well. We could even say that testing in accordance with VDE 0751 can be performed instead of testing per VDE 0701/0702.

WHAT IS AN ELECTRICAL MEDICAL DEVICE?

An electrical medical device is a device that includes an application part, or which transfers energy to or from the patient or displays an energy transfer of this sort, and for which the following applies:

- The device is connected to mains supply power
- The intended purpose of the device, as specified by the manufacturer, is for use:
  - In the diagnosis, treatment or monitoring of a patient
  - In compensating or alleviating an illness, an injury or a handicap.

MEDICAL TESTING TECHNOLOGY AT ITS FINEST

SECULIFE function testers have been specially developed for testing those medical devices which are used most commonly in clinics – directly at the patient. Great importance is placed upon efficiency and reliability when performing measurements on these devices. The great variety of manufacturers and models of monitoring and therapeutic devices also necessitates high levels of compatibility.

Extremely high-performance devices are required for the execution of measuring tasks in the field of medicine. On the one hand, they have to be able to cope with the complexity of the required tests, and on the other hand, they must assure high levels of accuracy for each individual measurement. Gossen Metrawatt meets these requirements with its SECULIFE range of safety testers. The new measuring instruments combine decades of experience gained by the international market leader in the field of electrical measuring technology with innovative technical solutions.

Download the Seculife Medical Device Catalogue here:
https://www.gossenmetrawatt.com/resources/marcom/kataloge/2013-14_k_med_gb_v1.pdf