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EN 60601-2-5 Ultrasonic Physiotherapy Equipment

Background

All electro-medical devices and systems have to comply with the Medical Devices Directive MDD 93/42/EEC. The protective goals of the directive can be demonstrated by the application of standards of the EN 60601-x-xx series.

Due to the special characteristics of therapeutic ultrasound devices, additional safety aspects beyond the requirements of EN 60601-1 have to be observed. These special requirements are laid down in EN 60601-2-5.

This Med-Info outlines the requirements of EN 60601-2-5 for therapeutic ultrasound devices.

Why are there additional requirements for therapeutic ultrasound devices?

Ultrasound therapy is a widely used method for the treatment of diverse diseases. Defined limits for ultrasound intensity have to be observed so that ultrasound physical therapy can be applied safely. In addition, testing of acoustical output control and performance accuracy of the device is defined to guarantee safe planning of therapeutic measures and to minimize hazards for the patient.

Which additional requirements result from EN 60601-2-5?

The general requirements include the criteria on "essential performance": The special safety-relevant aspects of ultrasound physical therapeutic systems refer to the safe use of the device for patient and user. Therefore, maximum values for ultrasound intensity and surface temperature on the ultrasound treatment head are defined. If the acoustic output of the device can be adjusted, this intensity control is subject to certain requirements on accuracy. The compliance with these requirements can only be tested by measuring the acoustic field characteristics and the output power. Furthermore, there are special conditions for testing the electromagnetic compatibility as well.

The instructions for use and the technical documentation have to include respective data on the acoustic power and acoustic field characteristics.

How are acoustic output parameters measured or calculated?

Two different methods of acoustic measurement form the basis for both the calculation of acoustic output values such as ultrasound power and intensity and the calculation of derived parameters on the acoustic field characteristics.

Acoustic pressure under free field conditions is determined by using hydrophone measurements in water. Besides the measurement of maximum acoustic pressure and intensity in the field, this also gives information on geometric field distribution (measurement procedures according to EN 61689). Furthermore, measurement of the acoustic power is carried out using a radiation force balance according to EN 61161. Using these methods, the compliance, the maximum intensity limit and the accuracy of the output control for the acoustic power/intensity can be tested.

What is new with IEC 60601-2-5:2009?

The main changes compared to the EN 60601-2-5:2000 are:

- Essential performance parameters are defined
- Measurements of ultrasound-related parameters are now based on IEC 61689:2007
- New requirement regarding dielectric strength test of transducer assemblies included
- New requirement regarding the measurement of the temperature of the transducer defined

Which measurements can be carried out by TÜV SÜD?

In addition to electrical safety testing of active medical devices, TÜV SÜD Product Service can also provide measurements and calculation of acoustic output parameters as defined in EN 60601-2-5. This is done in an ultrasound test lab, which is part of the TÜV SÜD Product Service test laboratory in Munich.

Duration and expenses for acoustical testing depend on the number of treatment head types and possible system settings.

Further services of the ultrasound laboratory

- Individual tests and measurement of acoustic fields and acoustic power up to 40 MHz
- Measurements on diagnostic ultrasound systems:
  - Acoustic measurements according to FDA requirements (track 1 and track 3)
  - Measurement of the Doppler sensitivity and accuracy according to FDA requirements
  - Acoustic measurements according to EN 61157
- Measurements on ultrasound surgery systems

Your contact partner at TÜV SÜD Product Service can provide further information.

Mathias Kuhn
Phone: +49 89 5008 4603
E-Mail: mathias.kuhn@tuev-sued.de

TÜV SÜD Product Service GmbH, Medical and Health Services, Ridlerstr. 65, 80339 Munich
www.tuev-sued.com/medinfo