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EN 60601-2-37:2008+A1:2015 diagnostic ultrasound devices

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 guaranteed by the application of standards of the EN 60601-x-xx series.

Due to the special characteristics of diagnostic ultrasound devices, additional safety aspects beyond the requirements of EN 60601-1 have to be observed. The special requirements resulting from this are laid down in the EN 60601-2-37 standard.

This Med-Info outlines the requirements of EN 60601-2-37:2008+A1:2015 for diagnostic ultrasound devices.

Why are there additional requirements for diagnostic ultrasound devices?

Ultrasound imaging is the most frequently applied imaging method in medical diagnostics. To safely apply ultrasound diagnostics, the impact of ultrasound on human tissue has to be considered. With regard to a possible hazard for the patient, two effects are relevant.

On the one hand, the ultrasound wave is subject to absorption in the tissue, thus resulting in a temperature rise. This effect is assessed with the help of acoustic power and intensity parameters. On the other hand, cavitation may occur in the negative pressure phase of the wave, thus leading to tissue damage. This effect is connected with the negative peak pressure within the ultrasound field. Safety parameters are deducted from acoustic pressure and power values on the basis of models for sound wave propagation in the human body. These parameters are the thermal index (TI) for the estimated temperature rise and the mechanical index (MI) describing the cavitation hazard.

Another safety aspect concerns the heating of the transducer surface in contact with the patient. This effect is not covered by the TI as this index only considers the heating in the acoustic field. However, due to acoustic absorption in the transducer surface material and due to the transducer heating of the transducer electronics, an additional temperature rise occurs.

Which requirements result from EN 60601-2-37?

The general requirements include the criteria on the essential performance. Here the special safety-relevant aspects of diagnostic ultrasound devices are listed:

- Signal distortion leading to measurement errors of diagnostically relevant parameters
- Display of inaccurate safety-related indications
- Production of unintended or excessive ultrasound output or heating of probes
- Unintended or uncontrolled moving of transducer probes intended for intracorporeal use

Diagnostic ultrasound devices therefore have to be marked accordingly, and the instructions for use have to include relevant information and data. In particular, a table with the maximum acoustic output values and the derived parameters (TI, MI) for every ultrasound mode of operation has to be included. If MI or TI exceed the numerical value of 1, this has to be indicated in the display of the device. The technical details of TI and MI are defined in EN 62359.

The surface temperature on ultrasound transducers has to be measured under simulated conditions of use and against still air. The temperature on the transducer surface must not exceed the limits defined by the standard. These limits depend on the intended use of the ultrasound probe. Furthermore, electrical safety tests (leakage current, high voltage tests) have to be carried out while the probe is immersed in physiological saline solution. There are also special testing conditions for electromagnetic compatibility exceeding the general requirements.

What is new with EN 62359:2011?

With the new edition of EN 62359, the definition of the TI is slightly modified. While the general model used to calculate thermal effects of ultrasound absorption in human tissue remains unchanged, the way the overall TI is calculated for combined operating modes is modifed. The new concept distinguishes between tissue heating expected close to the transducer (TI at surface) and the temperature increase expected for larger depth (TI below surface). With this change, the table for the declaration of acoustic parameters has to be changed. A new table format is given in Amendment 1 from 2015 to EN 60601-2-37:2008.

Caution: The TI at surface is not identical with the transducer surface temperature! The TI at surface is calculated solely from acoustic field data and therefore only relates to acoustic absorption in tissue. Transducer surface temperature is determined by thermal measurement and therefore also accounts for probe self-heating.

How are acoustic output values and parameters measured and calculated?

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

Acoustic pressure under free field conditions is determined by using hydrophone measurements in water according to EN 62127-1:2007+A1:2013. Besides the measurement of the maximum acoustic pressure and intensity in the field, this also gives information on geometric field distribution. Furthermore, measurement of the acoustic power is carried out using a radiation force balance according to EN 61161:2013.

Safety-relevant parameters are derived from the results of these measurements by model calculations according to EN 62359:2011.

Additionally, the maximum temperature on the transducer surface is also relevant for the safe use of diagnostic ultrasound equipment. The surface temperature is measured by thermosensors in the hottest spot of the transducer surface.

To evaluate the safety of the ultrasound device, those system settings maximizing each safety-relevant parameter have to be found for each probe type and for each mode of operation.

Which services can be offered by TÜV SÜD?

In addition to electrical safety testing of active medical devices, TÜV SÜD Product Service can also provide all required measurements and the calculation of acoustic output values as well as the measurement of surface temperature according to EN 60601-2-37. This is done in an ultrasound laboratory which is part of the TÜV SÜD Product Service test laboratory in Munich. The ultrasound test lab covers test facilities for measuring acoustic fields, acoustic power and surface temperatures.
Duration and expenses for acoustic testing depend on the number of ultrasound probes, the number of operating modes per probe and possible system settings.

Further services of the TÜV SÜD ultrasound laboratory

- Acoustic measurement 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
- Individual tests and measurement of acoustic fields and acoustic power
- Ultrasound field and performance measurements on ultrasound physical therapy systems according to EN 60601-2-5, EN 61161 and EN 61689
- Measurements on ultrasound surgery systems
- Functional safety assessment for ultrasound surgical systems and high-intensity equipment (HITU/HIFU)

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

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

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