Safety inspection of research equipment

All electrical equipment used during the study will be inspected regularly (once a year) by SOLO for electrical safety and general state of repair. This is in line with the regulations in the NEN-EN-IEC 62353:2014 guideline Medical electrical equipment – Periodic testing and testing after repair. If either the knowledge or the necessary diagnostic equipment is lacking at SOLO, the device will be submitted to the supplier or manufacturer for checking and/or inspection. Should the safety of the equipment be in doubt in-between inspections, or the device have displayed a fault, a compulsory inspection will need to be done in-between times. Equipment which is to be used outside of the laboratories must be recalled to FSW once a year for the regular inspection.

Inspection

The electrical inspection may only be carried out by an NEN-EN-IEC 62353 certified member of SOLO staff, or by the supplier or manufacturer of the device. The SOLO research technician has been trained and certified to carry out this inspection according to the guidelines of the NEN-EN-IEC 62353:2014 Medical electrical equipment.

Rejects

Should the equipment fail the electrical inspection or be in a state that may cause an unsafe situation, the equipment will be immediately taken out of service. If the equipment is unsafe, SOLO will if possible immediately have it repaired, or otherwise removed.

Once the equipment has been repaired according to the manufacturer's standards and the regulations as described in the NEN standards, a reinspection will have to take place.

Identification

All equipment (including battery powered) used during a study, must be marked with a unique identification label which allows the serial number, history, date of purchase, any repairs, logs etc. to be found in the SOLO database.

For equipment that has undergone electrical inspection according to NE-EN-IEC 62353, the regular inspection reports must be stored in the SOLO database. The log books in the laboratory will only record the inspection date.
Equipment without an identification label may not be used in the labs without prior permission from SOLO.