

# Calibration

The quality of the measurement and testing equipment manufactured by S.P.L. Elektronik and the calibrations of measuring and testing equipment carried out by S.P.L. Elektronik is determined by multistage, DIN EN ISO 9001 corresponding quality control and quality assurance measures. Quality control and quality assurance measures are ensured by the use of appropriate procedures, organizational instructions, work instructions and forms.

The safety testers and function testers manufactured by S.P.L. Elektronik are usually test devices. Compliance with the technical documentation results from the purpose of the test device. According to the manufacturer's specifications, the test certificate and the calibration certificate are necessary to meet the requirements of the respective test standard (e.g. IEC 62353), which the measuring devices used for the tests must be regularly checked and calibrated according to the manufacturer's specifications.

The measuring and testing devices are additionally subject to visual inspection and electrical safety testing in accordance with the VDE 0701-0702 before calibration at S.P.L. Elektronik.

The calibration at S.P.L. Elektronik usually involves verification, maintenance, software update and calibration of the test device. For this purpose, the test device is placed in the basic state and adjusting position is carried out. For the software used, in the context of the validation carried out in S.P.L. Elektronik in accordance with QM management, the conformity with the properties listed in the associated manual was established.

After final inspection and calibration, the measuring and testing equipment is given a calibration mark and a calibration certificate. S.P.L. Elektronik's calibration certificate are factory calibration. In addition, in our calibration appears, we specify the used reference normal (measuring devices) used to perform the calibration. The normals used are DIN EN ISO / IEC 17025 compliant lyre-returned to national normals. Their calibration certificate can be accessed through the link.

For test devices, which in turn are used for calibration tasks, an additional DIN EN ISO / IEC 17025 compliant calibration, which is carried out by a partner of S.P.L. Elektronik, can be performed. This is usually not necessary for the measuring and testing equipment used for the tests that are common in the medical field.

The test and calibration certificate created by S.P.L. Elektronik are automatically created, as stated on the documents, and do not require a signature. This procedure complies with the requirements of the ISO/IEC 17025:2018-03 standard, "General requirements for the competence of test and calibration laboratories." In this standard, section 7.8, "Reports of Results," subsection 7.8.1.2 Note 2 explicitly refers to the permissibility of electronic issuance. In subsection 7.8.2 "General Requirements for Reports" is required under 7.8.2.1 "o", "which must be designated the person (s) responsible for releasing the report (s) (not their signature). The calibration mark indicates subsection 7.8.4.3 the date of calibration.

The standard DIN EN 62353: 2015-08 used in the field of medical technology, as a rule of technology, also contains only the requirement under 6.1 "Result report" indent 7: When using electronic documentation, an assignment to the examiner / evaluator must be ensured.

The test adapter PA-100 / PA-X is used for performing the self-test. When using the internal self-test, perform the measurements specified in the manual. The self-test is used to determine the reasonableness of the voltage measurement, the leakage current measurements and correct functioning of the standardization. The self-test does not replace the calibration of the safety tester.

The warranted characteristics for PC operation of the safety tester and the functional tester of the S.P.L. Elektronik are guaranteed by the offered or authorized PC software programs. The warranted characteristics for PC operation are ensured by the above-mentioned software.

In coordination with the TÜEV CERT the entrepreneurial group of TÜV Rheinland / Berlin Brandenburg, for the normal, the purpose appropriate use of the measuring and testing devices of the S.P.L. Elektronik, an annual calibration interval is recommended. You find the date of the next calibration on the test mark. A change of this calibration interval can be accomplished by the user independently by his own responsibility, in coordination with the concerning quality assurance department.

Guidance Guide (ISO 10012 7.1.2): Data obtained from calibration and metrological confirmation histories, and advancing knowledge and technology, may be used for determining intervals between metrological confirmation. Records obtained using statistical process control techniques for measurements can be useful in determining whether or not to modify metrological confirmation intervals.

The necessary information for the calibration of the measuring and testing devices of S.P.L. Elektronik, in the form of instructions for process, software updates, hardware updates and calibration programs, are exclusively given from the S.P.L. Elektronik to authorized institutions.

For further inquiries we are to your disposal.

Other products in particular specified are registered trade marks or registered trade marks of their respective companies.

Yours sincerely

**S.P.L.**  
Elektronik