

PATCHMASTER PRO / FITMASTER PRO

Supporting GLP and FDA Regulations

Good Lab Practice (GLP) is becoming an increasingly more important aspect in the organization and daily life of commercial laboratories. This is especially so since the Food and Drug Administration (FDA) is requiring conformity to a set of GLP rules for data used in FDA applications (21 CFR Part 11). Any research entering the commercial world will be faced with the question of how reliable data and results were acquired and stored. Is it still possible to know exactly how the data were gathered? Who was the person doing the experiment? What were the exact parameters (e.g. amplifier gain? last calibration of instruments?). Suddenly, it becomes apparent that it would be a big advantage if one had applied at least a minimal set of GLP rules.

HEKA has always set the highest standards for electrophysiological data acquisition software. Currently, academic laboratories around the world are utilizing numerous features built within our software that enable them to conduct experiments and manage data confidently and with good lab practices in mind. To comply, however, with new FDA regulations and satisfy the requirements of commercial customers, HEKA has designed the PATCHMASTER PRO and FITMASTER PRO software.

PATCHMASTER is a data acquisition and analysis program package for patch clamp experiments which offers features meeting the highest standards of modern electrophysiology. This software, running on PC-based and Macintosh computers, offers a variety of novel procedures aimed to make electrophysiological research more versatile and efficient. With PATCHMASTER, experimental design, performance, and analysis become much more flexible, giving rise to a high degree of automation and standardization. (Please refer to the product information about "PATCHMASTER".)

FITMASTER is a data analysis and fitting program package which works on data acquired with PATCHMASTER.

PATCHMASTER PRO and FITMASTER PRO are designed to support, in addition to PATCHMASTER and FITMASTER, a set of Good Lab Practice (GLP) standards for data acquisition and handling, as established by the Food and Drug Administration (FDA) (21 CFR Part 11).

PATCHMASTER PRO and FITMASTER PRO provides various tools for customization of an experimental procedure. Custom specific procedures can be set up to make sure that all experiments are performed in the same manner.

Online data checking for validity of acquired data. Critical parameters such as access resistance or seal resistance are checked before each acquisition. In case those parameters are out of range, the data are marked "invalid" to make sure that they are not used for further analysis.

Although PATCHMASTER PRO can be run with any patch clamp amplifier, full functionality is best achieved when run with HEKA's computer controlled and programmable EPC 9 and EPC 10 family of amplifiers.

HEKA, in addition, offers services during the validation process. The HEKA staff helps creating User Requirement Specifications (URS) as well as performs Installation Qualifications (IQ) and Operational Qualifications (OQ) of PATCHMASTER PRO / FITMASTER PRO setups. For details please contact HEKA.

PATCHMASTER PRO provides the following features to support strict GLP and FDA rules.

Electronic Signature

- The log-in and log-out with signature and password is enforced, and its entry verified.
- The signature is stored in the data file.
- The signature can be used to automatically generate the filenames according to a set of rules, e.g. [date][user ID][test no].
- The signature is always exported during data export as an additional field. In case of print-outs, the signature is printed on each page.
- Login actions, including timestamps, are recorded in a secured audit file.

Audit Trail

- An audit trail is generated.
- The content of the audit trail file can be customized by the administrator.
- Audit trail files can be generated per user, per data file or per session.

Access Control

- A log-in is required for any action.
- Password expiration.
- Four levels of access can be specified for each user (User, Supervisor, Quality Manager, Administrator).
- The required access level for most functions can be defined by an administrator.
- Inactivity Locking

Data Integrity

- All files can be checked using CRC (cyclic redundant checksum) support.
- All files generated in a session are combined into one "bundle" file.
- Blocking of the possibility to delete data records during data acquisition, i.e. when the data file is opened with write permission ("New" and "Modify").
- Data can be encrypted.

Hardware Verification

- At the start of the program, the connected amplifier and its functionality can be verified.
- The identity of the amplifier is stored with the parameters in the data file.
- Verification that the calibration files and the field test protocols are newer than a user defined time span.

FITMASTER PRO can be operated in a PATCHMASTER PRO environment. It adds the following features to support strict GLP and FDA rules.

Data Integrity

- *FITMASTER PRO opens data files generated with PATCHMASTER PRO in read only mode. No change of raw data is possible.*
- *Analysis results generated by FITMASTER PRO are stored in a data tree structure which links the results directly to the corresponding raw data.*

Data Export

- *Export of analysis results and graphs for further processing or archivation is supported.*

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