Declaration regarding FDA- and GAMP-instruction

FDA-rule 21 CFR Part 11 "Electronic Records and Electronic Signatures" & GAMP "Good Automation Manufacturing Practice" for LiquiSonic® Ultrasonic Measurement systems

General

Device: LiquiSonic® Controller 10/20/30/40/50
Firmware: 108.20.210

Questions and answers related to 21 CFR Part 11

11.10(a)

Q	Is it possible to see on the system whether records have been altered?
A	Yes. User activities (i.e. user logins, product calibration, product change, change of date and time) are logged by controller.

11.10(b)

Q	Is the system capable of producing accurate and complete copies of records in electronic form in due time?
A	Yes, there are two possibilities: binary backups (whole data) on a CF card saving selected data as datasheets (html) using SonicWork
Q	Is the system capable of producing accurate and complete copies of records in paper form in due time?
A	Yes, by printing the html datasheets.

11.10(c)

Q	Are there utilities available to ensure that records captured using one version of the software will be readable when the software is no longer available?
A	Yes, current configuration can be adopted during firmware update. Recorded data are stored in a standard file format (csv, html).

11.10(d)

Q	Can the system access be limited to authorized persons only?
A	Yes, optionally the system can be equipped with a "user administration" component. Using this option, all users have to enter username and password before entering the service menu.

11.10(e)

Q	Is there a secure, computer-generated, time stamped audit trail (log files) that records the date and time of operator entries and actions that create, modify or delete electronic records?
A	Yes.
Q	Upon making a change to an electronic record, is previously recorded information still available (not obscured by the change)?
A	No.
Q	Are there utilities available to ensure that an electronic record' s audit trail captured using one version of the software will be readable when that software is no longer available?
A	Yes, recorded data are stored in standard file format (csv).
Q	Is the audit trail available for review and copying?
A	Yes.
Q	Is it possible to initiate automatically and on a regular basis a backup operation of all log files, audit trails and data files, either by the system itself or by means of third-party software, while the system remains online?
A	Yes. Complete backups (configuration, event log) can be generated by the system itself. Data are stored on a CF card, which is accessible as a network share while the system is running.

11.10(f)

Q	If the sequence of system steps or events is important, can this be enforced by the system?
A	n/a

11.10(g)

Q	Does the system ensure that only authorized individuals can use the system, electronically sign records, access the operation or computer system input or output device, alter a record or perform other operations?
A	By using the program option “user administration”, it is ensured that changes can be done only by authorized users.

11.10(h)

Q	If it is a requirement of the system that data or instructions can only come from certain input devices, does the system checks the validity of the source of any data or instructions received?
A	n/a

11.50

Q	Do signed electronic records contain the following related information: - The printed name of the signer (username alone is not sufficient)? - The date and time of signing? - The meaning of the signing (e.g. approval, review, etc.)?
A	All events are stored together with date and time. Login attempts (successful or failed) are also stored in the event log. The LiquiSonic system does not make a difference between username and real name. But the username is not restricted to be a single word. So the username can be identical to the real name.
Q	Is the above-mentioned information shown on all screen based and printed copies of electronic records?
A	Events are shown on the screen (event viewer) sorted by time in descending order.

11.70

Q	Are electronic signatures linked to their respective electronic records to ensure that they cannot be cut, copied or otherwise transferred by ordinary means?
A	Event log entries are protected against manipulation. It is not possible to remove or duplicate entries.

11.200(a)(1)

Q	Are non-biometric signatures made up of at least two components?
A	Yes, password and username.

11.200(a)(1)(i)

Q	When non-biometric signings are made during continuous sessions, can the password be executed at each signing? (Both components must be executed at the first signing).
A	No. After first signing (username and password) multiple actions can be done without signing again.

11.200(a)(1)(ii)

Q	If signings are done in a continuous session, can both components of non-biometric electronic signatures be executed with each signing?
A	No. See above.

11.300(b)

Q	Can the system be configured to automatically prompt the user to change his password in case of expired passwords?
A	No.
Q	Can the system be configured to detect unauthorized access attempts?
A	Yes. Every login attempt (successful and failed) is recorded.

11.100(a)

Q	Are user ID codes unique to an individual?
A	Yes, as long usernames are unique. This has to be controlled by the system administrator while setting up user accounts.

11.200(a)(3)

Q	Would the attempt to falsify a non-biometric electronic signature require the collaboration of at least two individuals?
A	Falsification is only possible with the knowledge of username and password. Passwords are secret to each user and usernames can be chosen arbitrary.

11.300(a)

Q	Can the system be configured to maintain the uniqueness of identification codes (username & password)?
A	Not automatically. This has to be done by the administrator.

11.300(b)

Q	Can the system be configured to enter an expiration period for identification codes (username & password)?
A	No.
Q	Can user accounts be disabled or removed?
A	Yes.

11.200(b)

Q	In case of biometric signatures: has it been proven that signatures can be used only by their genuine owners?
A	n/a

Software supplier questions

General

Q	What is the size of your offices in terms of staff numbers?
A	36
Q/A	How many of these are: - Management?: 3 - Staff?: 25 - Development?: 5 - Support?: 3
Q/A	What is your current IT-infrastructure with regard to: - Servers?: Dell - Operating System(s)?: Windows , Linux - Database(s)?: SQL
Q	What other products than the subsequent software does your office support?
A	None.
Q	Do you sub-contract any software development or support work to third party organizations?
A	No.

Quality Control

Q	Do you have ISO9001 certification for the subsequent software?
A	Yes.
Q	Has your software had any other formal quality certification other than ISO?
A	No.
Q	Have any of your customers had FDA audits? If yes, can you provide contact?
A	Probably yes. We are not allowed to provide contact to other customers.
Q	Are you aware of GAMP procedures?
A	Yes.
Q	Do you use other formal life cycle procedures than GAMP?
A	No.
Q	Do you have documented system design records (Functional specifications, Flow Charts, Design Specifications, …)?
A	Yes.
Q	Do you measure the build system against the design in a formal way?

A	No.
Q	Do you have documented test records?
A	Yes.
Q	During testing, do you use simulation processes? If yes, please explain.
A	Yes. For some tests we generate input values (stimuli) and compare the test results against pre-calculated values.
Q	Do you have formal change management procedures? If yes, please explain.
A	Yes. According to DIN ISO 9001.
Q	Do you have formal acceptance testing protocols?
A	Yes.
Q	Is the system supplied with a user manual?
A	Yes.
Q	Are user manuals kept up to date with subsequent releases of the software?
A	Yes.
Q	Do you use quality and/or project plans? If yes, please briefly describe.
A	Development projects are monitored and controlled by means of project plans. Quality tests are essential parts of development projects.
Q	Do you carry out code revisions?
A	Yes. We use CVS.
Q	Do you use structured naming conventions within the code to aid visibility? If yes, please explain briefly.
A	Yes. We have coding guidelines similar to: http://micrium.com/download/an2000.pdf

Testing

Q	What is the testing strategy used?
A	unit tests (low level) system tests (high level)
Q	Who designs test procedures?
A	Developers → unit tests Developers together with QA members → system tests
Q	Explain how your testing documentation is controlled?
A	Test protocols are proved by the project leader. Software is not released until all tests are passed.

Release

Q	How do you alert the customer with regard to problems with the software once it is released?
A	Customer will be informed about the problem. A firmware update will be performed, if necessary.
Q	What assistance is provided to the customer to upgrade from an earlier version?
A	Normally the device firmware stays unchanged. But if the customer wants to upgrade to a newer version, SensoTech performs the upgrade or helps the customer to perform the upgrade.
Q	Not all customers will be on the same release. How do you ensure your knowledge of this is tied into subsequent releases?
A	SensoTech tracks the complete hardware and software revision of every single device, so we can decide, what update/change is possible and what is not.
Q	How do you prevent the wrong release being issued to a specific customer?
A	See above.
Q	How do you guarantee that data recorded in one version of the software will be readable in a newer version of the software?
A	Data are recorded in a standard file format (.csv)
Q	How many versions may the software, as installed at the customer's site, differ from the latest release in order that you provide full support?
A	There is no limitation.
Q	What is your definition of a software version?
A	A software release is characterized by a certain development stage (functionality) of the device. For this version the state of all sources is explicitly assigned.

Change control

Q	Do you have formal standard operating procedures to define precisely how your change control operates?
A	Yes. For every change request (i.e. add new functionality) a task is created. This task is an electronic document, which is part of SensoTech's system database. The state of task processing is documented there by the project members and checked by the project leader.
Q	How do you authorize changes?
A	Source code access is granted to authorized developers only. Every change to the firmware is tracked by the version control system. When implementation is done, software tests are performed and documented. After evaluation of the test protocols a new firmware is released by the project leader.
Q	Is the 'Quality Function' involved in signing-off test procedures?
A	With the system test (by QA member) it is checked whether a software change or enhancement meets the customers requirements.

Supporting procedures

Q	How do you notify customers about future releases?
A	This is done by: exhibitions, sales representatives, newsletters.
Q	What is your level of disaster recovery to protect your business and customers should you have a disaster occur?
A	A data backup is performed daily. Backups are kept safe inside and outside the company.
Q	What are your support services to the customer?
A	Application support Teaching IQ/OQ
Q	What are your methods for handling customer complaints?
A	Customer feedback is gathered and evaluated according to DIN EN ISO 9001.

Magdeburg-Barleben, 21. Januar 2011

Signature: _____

ISO 9001 - Certificate: 78 100 6976-0