

Checklist Data Integrity	UVS 3.x
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General Information	
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Software Information	
General Information	
Software	UVS Client/Server
Software version	3.x (<i>valid from Version 3.1</i>)
Software for 21 CFR Part 11 Compliance?	yes

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1 Data backup and data modification			
Nr.	Checkpoint	Conclusion	Comment
	Is all regulatory relevant data saved as E-Record?	Is all data automatically saved by the software? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
	Does the system produce precise and complete copies in human readable and electronic form?	Are the E-Records human readable and complete? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
	Prevention of modification of GxP relevant data. <u>Clarification:</u> Any modification of GxP relevant data must be impossible via system functions provided by the software or interfaces.	Is any undocumented modification of GxP relevant data generally prohibited? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Does the software prohibit the deletion of data? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Is any data loss by overwriting existing data prohibited? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	All methods and acquired data are revisioned and stored in an MS SQL data base on a data base server. Any modification leads to the creation of a new revision. All actions are logged in Audit Trail which is linked to the data set. Any measured values that are not automatically saved cannot be displayed.
	Generating reports from software (e.g. processing) must retain the original raw data.	Is all raw data retained when processing the data / generating a report? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
	How is data backup handled? Is it a data base system or a file based system?	Is it a data base system? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	MS SQL data base, which is situated anywhere in the LAN on a server.
	Does the software provide an integrated backup functionality?	Automatic or manual data backup function available? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Data backup is a basic functionality built-in the MS SQL Server – configuration of the data backup is done in MS SQL Server.

2 Reprocessing			
Nr.	Checkpoint	Conclusion	Comment
	<p>Is data reprocessing possible (i.e. calculating new results based in the raw data)?</p> <p>If “No”, please mark all following checkpoints of this paragraph with “n.a.”</p>	<p>Is Reprocessing possible? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Modifications can be performed by users with sufficient permissions. As soon as any modification is applied, no print-out or data export can be made as long as the modification is not saved. As soon as the modification is accepted, a new revision is generated.</p>
	<p>If any reprocessing is performed, will the first report be retained?</p>	<p>When reprocessing, does the software prevent overwriting or deleting the first report? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p>	<p>Every prior revision is stored in the data base and can be recalled at any time.</p>
	<p>Do the reports show if data has been reprocessed?</p>	<p>Is reprocessing shown on the report? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p> <p>Is reprocessing shown in the E-Records? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p>	<p>Yes, all revisions and the complete Audit Trail of all revisions is presented in the report.</p> <p>Yes, same as in report.</p>
	<p>Does the system force to enter a comment if data is modified?</p>	<p>Is entering a comment required in case of modifying data? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p>	<p>A comment of at least 5 non-empty characters must be entered.</p>
	<p>Does the software provide different levels of permissions for modifications?</p> <p><u>Clarification:</u> Does the software provide a way to exclude e.g. the permission to modify on a per-user basis?</p>	<p>Is there an application-based role concept to provide different permissions for data modification? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p>	<p>Yes, permissions are defined in user roles and can be customized by the administrator(s). Roles can also be linked to security groups of the domain and are therefore applied automatically when a user logs on with his/her domain account (Active Directory).</p>

3 Data Traceability			
Nr.	Checkpoint	Conclusion	Comment
	<p>Does the software provide the possibility to conduct at least 2 or more measurements simultaneously.</p> <p>When performing simultaneous measurements, the acquired data must be stored separately or project related and must be linked unambiguously.</p>	<p>Simultaneous measurements possible? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Are these measurements labelled and stored unambiguously and separate? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p>	<p>All photometric systems store their data in the same data base, but all raw data is linked to the acquiring photometric system. Each photometric system can be linked to workgroups and users of one workgroup are only allowed to view data acquired by users of their own workgroup. Data belonging to another workgroup cannot be viewed.</p>
	<p>Is generated data linked to a specific user when operating in multi-user-mode.</p> <p><u>Clarification:</u> While a data acquisition is running, an attempt is made to log in with another user account. There must be no access to other user profiles.</p>	<p>Multi-user mode operation is possible while data acquisition is running? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>In case of multi-user mode operation, acquired data is linked unambiguously to one specific user? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p>	<p>Additional users can start another instance of the software. In this additional software instance the permissions of the logged-in user are applied. This user and his actions is logged separately in the Audit Trail.</p>
	<p>Audit Trails must be logically linked to the stored data sets.</p>	<p>Are all data sets and the corresponding audit trails linked? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Yes, each data set has its own audit trail from the first creation and throughout all revisions permanently linked to the data set.</p>
	<p>The system must verify the identity of the current photometric system.</p> <p><u>Clarification:</u> The identity of the photometric system is verified by the software.</p>	<p>Can the software unambiguously identify the photometric system? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>The instrument serial number is read during initialisation of the software and is permanently stored as part of the data set.</p>

4 Audit-Trail			
Nr.	Checkpoint	Conclusion	Comment
	<p>It must be checked if an Audit Trail is present as part of the regulatory relevant data.</p> <p><u>Clarification:</u> If “No”: please mark the following checkpoints of this chapter as “n.a.”.</p>	<p>Is an Audit Trail present? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>With each data set an Audit Trail is generated from the time of first generation and is permanently linked to the data set. All actions, from creation to the last modification, are recorded throughout every revision.</p>
	<p>Is overwriting or deleting entries of the Audit Trail prevented?</p>	<p>Is overwriting or deleting entries of the Audit Trail prevented? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p>	<p>All entries of the Audit Trail are stored in the data base and therefore cannot be manipulated or deleted in any ways.</p>
	<p>Are all creations / modifications performed on electronic records by any user recorded at the moment of the event (with date and time) in the Audit Trail?</p> <p><u>Clarification:</u> The entries in the Audit Trail must present the following bits of information: Date and Time / User / Type of modification / Seamless and chronological record of all creations (e.g. data acquisition) / modifications</p>	<p>All mentioned information is present in the Audit Trail? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p>	
	<p>Does the Audit Trail record all modifications performed on data?</p> <p><u>Clarification:</u> The Audit Trail must contain: Explanation / comment about the performed modifications previous and current values reprocessing (new report generation)</p>	<p>Does the Audit Trail record explanations for the performed data modifications? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p> <p>Does the Audit Trail record previous and new values? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p> <p>Does the Audit Trail record data reprocessing? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p>	

4 Audit-Trail			
	<p>Are Audit Trails accessible, human readable, reproducible and unchanged during the whole retention period?</p>	<p>Are Audit Trails backed up? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p> <p>Can Audit Trails be reproduced unchanged in human readable form? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p>	<p>Yes, in MS SQL data base.</p> <p>Yes, by means of the Trail-Report. The Trail-Report present is the analysis report by default.</p>
	<p>Is the Audit Trail generated automatically by the system? Is disabling the Audit Trail by a user prevented?</p>	<p>Audit Trail is generated automatically? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p> <p>Is disabling the Audit Trail by a user prohibited / prevented? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p>	
	<p>Does the Audit Trail show which user role the user was acting in (e.g. as regular user or admin)?</p>	<p>Does the Audit Trail record the user role of the user? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p>	

5 Data Protection

Nr.	Checkpoint	Conclusion	Comment
	<p>It must be checked if software access is password protected.</p> <p><u>Clarification:</u> If “No”: please mark the following checkpoints of this chapter as “n.a.”</p>	<p>Does the software incorporate password protection? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>	
	<p>It must be checked if the password protection can be linked with Active Directory.</p>	<p>Is the password protection coupled with Active Directory Login? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p>	
	<p>It must be checked if a user gets blocked (lock-out) in case of entering a false password several times.</p> <p><u>Clarification:</u> A user account will be blocked in case of exceeding the allowed number of failed password attempts. (max. 10 attempts).</p> <p>Unblocking of the user account will occur at the earliest after 30 min or in case of manual intervention.</p>	<p>Is an account blockage utility in place? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p> <p>The maximum allowed number of failed attempts equals 10 or less? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p> <p>Are the conditions for unblocking an account fulfilled? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p>	<p>Yes, after 5 consecutive failed login attempts, the offending user account is automatically blocked. Unblocking the user account must be performed by an admin.</p>
	<p>Check for automated log out of a user after a defined period of time</p> <p><u>Clarification:</u> The logged in user will be logged out after being inactive for 15 minutes.</p>	<p>Does the software log out inactive users after 15min? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p>	<p>The time period after which the automated log out occurs can be defined by the admin.</p> <p>Furthermore an automated log out can also be accomplished by automatically locking the workstation in the operating system. Any running data acquisition will finish in the background, so that no data is lost.</p>

5 Data Protection			
Nr.	Checkpoint	Conclusion	Comment
	<p>It must be checked if a user is required to enter a new password when logging in for the first time.</p> <p><u>Clarification:</u> After assigning a password to a new user, the user is required to enter a new password on first login.</p>	<p>Does the software require the user to change his/her password on first login?</p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p>	<p>Yes, locally defined users are required to change their initial password when logging in to the software for the first time.</p> <p>This does NOT apply if domain login (Active Directory) is active. In this case, password validity / life time is checked by the domain, not the application.</p>
	<p>It must be checked if the password minimum requirements are fulfilled.</p> <p><u>Clarification:</u> Minimum requirements for the password are as follows: 1. Minimum length: 8 characters 2. The password contains at least 3 of the following criteria: upper case characters (A...Z) lower case characters (a...z) Arabic numbers (0...1) symbols (!,@,#,\$...)</p>	<p>Does the software enforce passwords that comply with the mentioned password restrictions or can the restrictions be defined in the software settings?</p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p>	<p>This is achieved by domain login (Active Directory).</p> <p>Domain login allows to define the password security restrictions in detail.</p>
	<p>Is there an Audit-Trail of user events?</p> <p><u>Clarification:</u> An Audit-Trail of user events must be in place and keep track of the following actions: Login and logout events Signing Events Date and Time Creation, locking and deletion of user accounts Modification of user roles / permissions User who performs modifications</p>	<p>Does the Audit-Trail record the mentioned user events?</p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p>	<p>Login and logout events are recorded in the Audit-Trail.</p> <p>Administrative interventions: Creating <i>local</i> users or modifying permissions will not be recorded in the current software version. This feature is planned with high priority for subsequent patches or the coming release version.</p>

5 Data Protection

Nr.	Checkpoint	Conclusion	Comment
	<p>Is a password lifetime / validity period of 90 days enforced by the software?</p> <p><u>Acceptance criteria:</u> The password settings allow to define a lifetime interval / validity period of 90 days which is enforced by the software.</p>	<p>Will the software enforce changing the user password after 90 days? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p>	<p>Does not apply for local users (local user access can be switched off by admin(s)).</p> <p>When using domain login (Active Directory) the password restrictions as defined in Active Directory apply.</p>

6 User Management

Nr.	Checkpoint	Conclusion	Comment
	<p>It must be checked if the software contains a user management.</p> <p><u>Clarification:</u> If “No”: please mark the following checkpoints of this chapter as “n.a.”.</p>	<p>Is a user management in place? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Yes</p>
	<p>Are different levels of permissions (roles) available in user management?</p> <p><u>Clarification:</u> Admins must have separate permission levels: Admin separated from User / Superuser separated from User</p>	<p>Is an application-based role concept in place? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p>	<p>User roles can be defined and assigned individually by the admin(s). Additional user roles can be created and defined, so that different concepts of permission assignment can be established.</p>

6 User Management			
Nr.	Checkpoint	Conclusion	Comment
	<p>It must be checked if all user accounts are personalized.</p> <p><u>Clarification:</u> Usage of a generic, un-personalized user account must not be allowed (e.g. general service accounts or general admin accounts)</p>	<p>All user accounts are personalized? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p>	
	<p>Does the software prevent the creation of identical IDs (user codes) and the re-assignment of user IDs to other users during the lifetime of the system throughout the whole application?</p>	<p>Are user accounts linked unambiguously to one specific person? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p>	
	<p>It must be checked that user management is accessible to the admin account only.</p>	<p>User management is only accessible with admin permissions? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p>	
	<p>It must be checked if the admin account can be denied the permission to perform data acquisition.</p>	<p>Does the software allow to restrict the admin role from being able to perform routine data acquisition / analysis? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p>	<p>By default an admin cannot create methods nor perform data acquisition nor view acquired data sets.</p>

7 Report / Paper Printout

Nr.	Checkpoint	Conclusion	Comment
	<p>It must be checked if the software generates a report that references all raw data.</p> <p><u>Clarification:</u> The following bits of information must be contained in the report: Reference to the sample (Identifier, e.g. charge no. or batch no.) Reference to the equipment used (e.g. instrument ID) Date and time of the analysis / data acquisition Instrument parameters (e.g. measuring mode)</p>	<p>Does the software create a report with all mentioned bits of information? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p>	<p>By default, all mentioned bits of information are contained in the report.</p> <p>Report-templates may be adjusted by users with specific permissions via the Report Manager. All templates are stored in the data base.</p>
	<p>For archiving reports in paper form, it must be checked if at least the following additional information can be printed on the paper report: User Date and time of printout Page number of total number of pages Data path (where the data is stored) Name of record Software and software version, with which the data has been created</p>	<p>Does the paper report show all mentioned bits of information? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p>	<p>The data path is not shown as path, because all data is stored in the MS SQL data base</p>
	<p>It must be checked that the printed data correspond to the data in the electronic system and that all data can be linked unambiguously to the printouts</p> <p><u>Clarification:</u> Modifications and comments must be recorded on paper as well as in E-records</p>	<p>Can the data shown on the paper printout clearly be referred to the E-records and do they match? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p>	

8 Electronic Signature

Nr.	Checkpoint	Conclusion	Comment
	<p>It must be checked if the software provides the capability of electronic signatures.</p> <p><u>Clarification:</u> If “No”: please mark the following checkpoints of the chapter as “n.a.”</p>	<p>Does the software provide electronic signatures? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>	
	<p>Electronic signatures must be designed in a way that they assure a true and permanent representation of the user’s action.</p> <p><u>Clarification:</u> Electronic signatures must be linked with the E-records and must be displayed and printed together with the electronic records. The signature must contain: User name in plain text Date and time including timezone information of the signature Significance of the signature (e.g. Author, review or approval)</p>	<p>Does the electronic signature feature fulfil the requirements lined out in the clarification? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p>	
	<p>All electronic signatures can be referred back to one person unambiguously</p> <p><u>Clarification:</u> This also implies that a user-ID cannot be assigned twice and that regulations are in place about identical names.</p>	<p>Can an electronic signature be referred to one person unambiguously? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.</p>	<p>Signatures are used in general together with Active Directory login (this can be configured by admin), whereby the signature role will be defined in the permission groups of the domain.</p> <p>Relying on the Active Domain, the uniqueness of a user ID is guaranteed.</p>

8 Electronic Signature			
Nr.	Checkpoint	Conclusion	Comment
	When using non-biometric signature, at least two independent means of identification shall be used. (e.g. user name and password).	Does the electronic signature consist of user name and password that have to be entered anew for each session? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.	This will be assured by the Active Directory domain, if domain login is used. Furthermore the software itself will enforce two-factor identification also for local users (if local users were allowed by an admin).
	Are electronic signatures permanently linked to the E-record and can they be restored?	Are electronic signatures permanently linked to the E-record and can they be restored? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.	
	It must be checked that copying, tampering or removing of a signature in the E-record is prevented. <u>Clarification:</u> The following actions must be prevented in terms of electronic signatures: <ul style="list-style-type: none"> • Removal • Copying • Transfer • Deletion • Tampering 	Is copying, tampering or removal of electronic signatures in the E-Record prevented? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.	An electronic signature is appended to the record in the data base and thus can neither be tampered, deleted, copied, transferred nor removed.

- End of File -