

21 CFR Part 11 Compliance Controls for trialwiseSCAN

Under 21 CFR Part 11, a “closed system” is defined as “an environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system” and an “open system” is “an environment in which system access is not controlled by persons who are responsible for the content of electronic records that are on the system.”

By this definition, trialwiseSCAN can be considered a “closed system”. System access to trialwiseSCAN is controlled by the same person (user/author) who is responsible for content within the app.

11.10 Controls for closed systems.

PERSONS WHO USE CLOSED SYSTEMS TO CREATE, MODIFY, MAINTAIN, OR TRANSMIT ELECTRONIC RECORDS SHALL EMPLOY PROCEDURES AND CONTROLS DESIGNED TO ENSURE THE AUTHENTICITY, INTEGRITY, AND, WHEN APPROPRIATE, THE CONFIDENTIALITY OF ELECTRONIC RECORDS, AND TO ENSURE THAT THE SIGNER CANNOT READILY REPUDIATE THE SIGNED RECORD AS NOT GENUINE. SUCH PROCEDURES AND CONTROLS SHALL INCLUDE THE FOLLOWING:

21 CFR Part 11 Regulation	Trialwise Controls	Customer Controls
(A) VALIDATION OF SYSTEMS TO ENSURE ACCURACY, RELIABILITY, CONSISTENT INTENDED PERFORMANCE, AND THE ABILITY TO DISCERN INVALID OR ALTERED RECORDS.	<p>trialwiseSCAN is validated for accuracy, reliability, and consistent intended performance. Validation documentation is controlled within the Quality Management System (QMS).</p> <p>The QMS includes a formal change control procedure and sequenced audit trail of changes.</p>	Completes a risk assessment
(B) THE ABILITY TO GENERATE ACCURATE AND COMPLETE COPIES OF RECORDS IN BOTH HUMAN READABLE AND ELECTRONIC FORM SUITABLE FOR INSPECTION, REVIEW, AND COPYING BY THE AGENCY. PERSONS SHOULD CONTACT THE AGENCY IF THERE ARE ANY QUESTIONS REGARDING THE ABILITY OF THE AGENCY TO PERFORM SUCH REVIEW AND COPYING OF THE ELECTRONIC RECORDS.	<p>trialwiseSCAN displays documents in a human readable form on-screen within the app.</p> <p>Provides documents in electronic form conforming to the PDF/A standard.</p>	
(C) PROTECTION OF RECORDS TO ENABLE THEIR ACCURATE AND READY RETRIEVAL THROUGHOUT THE RECORDS RETENTION PERIOD.	<p>Records are stored on-device in a siloed folder specific to the trialwiseSCAN app.</p> <p>Document retention is limited. Scanned records are transmitted from the app to an end-party at</p>	Retains documents generated and transferred from trialwiseSCAN.

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	<p>which time the retention period effectively ends and the document is deleted.</p>	
<p>(D) LIMITING SYSTEM ACCESS TO AUTHORIZED INDIVIDUALS.</p>	<p>Access to trialwiseSCAN requires biometric authorization by Touch ID or Face ID.</p>	
<p>(E) USE OF SECURE, COMPUTER-GENERATED, TIME-STAMPED AUDIT TRAILS TO INDEPENDENTLY RECORD THE DATE AND TIME OF OPERATOR ENTRIES AND ACTIONS THAT CREATE, MODIFY, OR DELETE ELECTRONIC RECORDS. RECORD CHANGES SHALL NOT OBSCURE PREVIOUSLY RECORDED INFORMATION. SUCH AUDIT TRAIL DOCUMENTATION SHALL BE RETAINED FOR A PERIOD AT LEAST AS LONG AS THAT REQUIRED FOR THE SUBJECT ELECTRONIC RECORDS AND SHALL BE AVAILABLE FOR AGENCY REVIEW AND COPYING.</p>	<p>Automatic. At time of creation a time stamp is created in UTC. This time stamp is recorded in the xmp metadata screen of the PDF document as per PDF/A standards.</p> <p>The original captured image is retained until the document is deleted from the system.</p>	
<p>(F) USE OF OPERATIONAL SYSTEM CHECKS TO ENFORCE PERMITTED SEQUENCING OF STEPS AND EVENTS, AS APPROPRIATE.</p>	<p>Automatic</p>	
<p>(G) USE OF AUTHORITY CHECKS TO ENSURE THAT ONLY AUTHORIZED INDIVIDUALS CAN USE THE SYSTEM, ELECTRONICALLY SIGN A RECORD, ACCESS THE OPERATION OR COMPUTER SYSTEM INPUT OR OUTPUT DEVICE, ALTER A RECORD, OR PERFORM THE OPERATION AT HAND.</p>	<p>Access to trialwiseSCAN requires biometric authorisation by Touch ID or Face ID. Documents are not electronically signed.</p> <p>Managed Folders can only be created via a process that verifies the user via an authentication code provided to that user.</p>	<p>For Managed Folders, verifies the identity of individuals linked to email addresses and the validity of documents authored and sent from trialwiseSCAN</p>
<p>(H) USE OF DEVICE (E.G., TERMINAL) CHECKS TO DETERMINE, AS APPROPRIATE, THE VALIDITY OF THE SOURCE OF DATA INPUT OR OPERATIONAL INSTRUCTION.</p>	<p>Access to trialwiseSCAN requires biometric authorization by Touch ID or Face ID.</p> <p>Whenever trialwiseSCAN is closed or the app goes into background mode (e.g. because of timeout), then authentication is again required.</p>	

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<p>(i) DETERMINATION THAT PERSONS WHO DEVELOP, MAINTAIN, OR USE ELECTRONIC RECORD/ELECTRONIC SIGNATURE SYSTEMS HAVE THE EDUCATION, TRAINING, AND EXPERIENCE TO PERFORM THEIR ASSIGNED TASKS.</p>	<p>Trialwise engineers have many decades of experience in the development of systems including medical device software and hardware incorporating ISO 13485 Medical Device Quality Management Systems and IEC 62304 Medical Device Software.</p> <p>Staff are trained in 21CFR Part11 and qualification and training documents maintained.</p>	<p>Evaluates and documents a user’s education, training, and experience.</p>
<p>(j) THE ESTABLISHMENT OF, AND ADHERENCE TO, WRITTEN POLICIES THAT HOLD INDIVIDUALS ACCOUNTABLE AND RESPONSIBLE FOR ACTIONS INITIATED UNDER THEIR ELECTRONIC SIGNATURES, IN ORDER TO DETER RECORD AND SIGNATURE FALSIFICATION.</p>	<p>Maintains policies and procedures that reflect responsibilities and requirements in the QMS.</p>	<p>Maintains policies and procedures that reflect user responsibilities and requirements. Store these documents within Document Control.</p>
<p>(k) USE OF APPROPRIATE CONTROLS OVER SYSTEMS DOCUMENTATION INCLUDING: (1) ADEQUATE CONTROLS OVER THE DISTRIBUTION OF, ACCESS TO, AND USE OF DOCUMENTATION FOR SYSTEM OPERATION AND MAINTENANCE. (2) REVISION AND CHANGE CONTROL PROCEDURES TO MAINTAIN AN AUDIT TRAIL THAT DOCUMENTS TIME-SEQUENCED DEVELOPMENT AND MODIFICATION OF SYSTEMS DOCUMENTATION.</p>	<p>User guides and release notes are provided as an electronic document available within the binary of each version of the app.</p> <p>Version control is an important part of the validation process. Revision control procedures maintain an audit trail of time sequenced changes to release notes (and software code) in a git repository.</p>	

11.30 Controls for open systems.

PERSONS WHO USE OPEN SYSTEMS TO CREATE, MODIFY, MAINTAIN, OR TRANSMIT ELECTRONIC RECORDS SHALL EMPLOY PROCEDURES AND CONTROLS DESIGNED TO ENSURE THE AUTHENTICITY, INTEGRITY, AND, AS APPROPRIATE, THE CONFIDENTIALITY OF ELECTRONIC RECORDS FROM THE POINT OF THEIR CREATION TO THE POINT OF THEIR RECEIPT. SUCH PROCEDURES AND CONTROLS SHALL INCLUDE THOSE IDENTIFIED IN 11.10, AS APPROPRIATE, AND ADDITIONAL MEASURES SUCH AS DOCUMENT ENCRYPTION AND USE OF APPROPRIATE DIGITAL SIGNATURE STANDARDS TO ENSURE, AS NECESSARY UNDER THE CIRCUMSTANCES, RECORD AUTHENTICITY, INTEGRITY, AND CONFIDENTIALITY.

trialwiseSCAN is considered a closed system. Section 11.30 is not applicable.

11.50 Signature manifestations.

21 CFR Part 11 Regulation	Trialwise Controls	Customer Controls
<p>A) SIGNED ELECTRONIC RECORDS SHALL CONTAIN INFORMATION ASSOCIATED WITH THE SIGNING THAT CLEARLY INDICATES ALL OF THE FOLLOWING: (1) THE PRINTED NAME OF THE SIGNER; (2) THE DATE AND TIME WHEN THE SIGNATURE WAS EXECUTED; AND (3) THE MEANING (SUCH AS REVIEW, APPROVAL, RESPONSIBILITY, OR AUTHORSHIP) ASSOCIATED WITH THE SIGNATURE.</p>	<p>Ensures that signed electronic records within the QMS contain information to clearly indicate the printed name of the signer, the date and time that the signature was executed, and the meaning associated with the signature.</p>	<p>Ensures that signed documents contain information to clearly indicate the printed name of the signer, the date and time that the signature was executed, and the meaning associated with the signature.</p>
<p>(B) THE ITEMS IDENTIFIED IN PARAGRAPHS (A)(1), (A)(2), AND (A)(3) OF THIS SECTION SHALL BE SUBJECT TO THE SAME CONTROLS AS FOR ELECTRONIC RECORDS AND SHALL BE INCLUDED AS PART OF ANY HUMAN READABLE FORM OF THE ELECTRONIC RECORD (SUCH AS ELECTRONIC DISPLAY OR PRINTOUT).</p>	<p>Maintains signed electronic records within the QMS in human readable form and in accordance with 21CFR Part 11 requirements.</p>	

11.70 Signature/record linking.

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<p>ELECTRONIC SIGNATURES AND HANDWRITTEN SIGNATURES EXECUTED TO ELECTRONIC RECORDS SHALL BE LINKED TO THEIR RESPECTIVE ELECTRONIC RECORDS TO ENSURE THAT THE SIGNATURES CANNOT BE EXCISED, COPIED, OR OTHERWISE TRANSFERRED TO FALSIFY AN ELECTRONIC RECORD BY ORDINARY MEANS.</p>	<p>Handwritten Signatures are linked to their electronic record and cannot be overwritten by ordinary means.</p> <p>trialwiseSCAN does not utilize electronic signatures.</p>	

Subpart C Electronic Signatures

trialwiseSCAN does not utilize electronic signatures. Subpart C is not applicable.