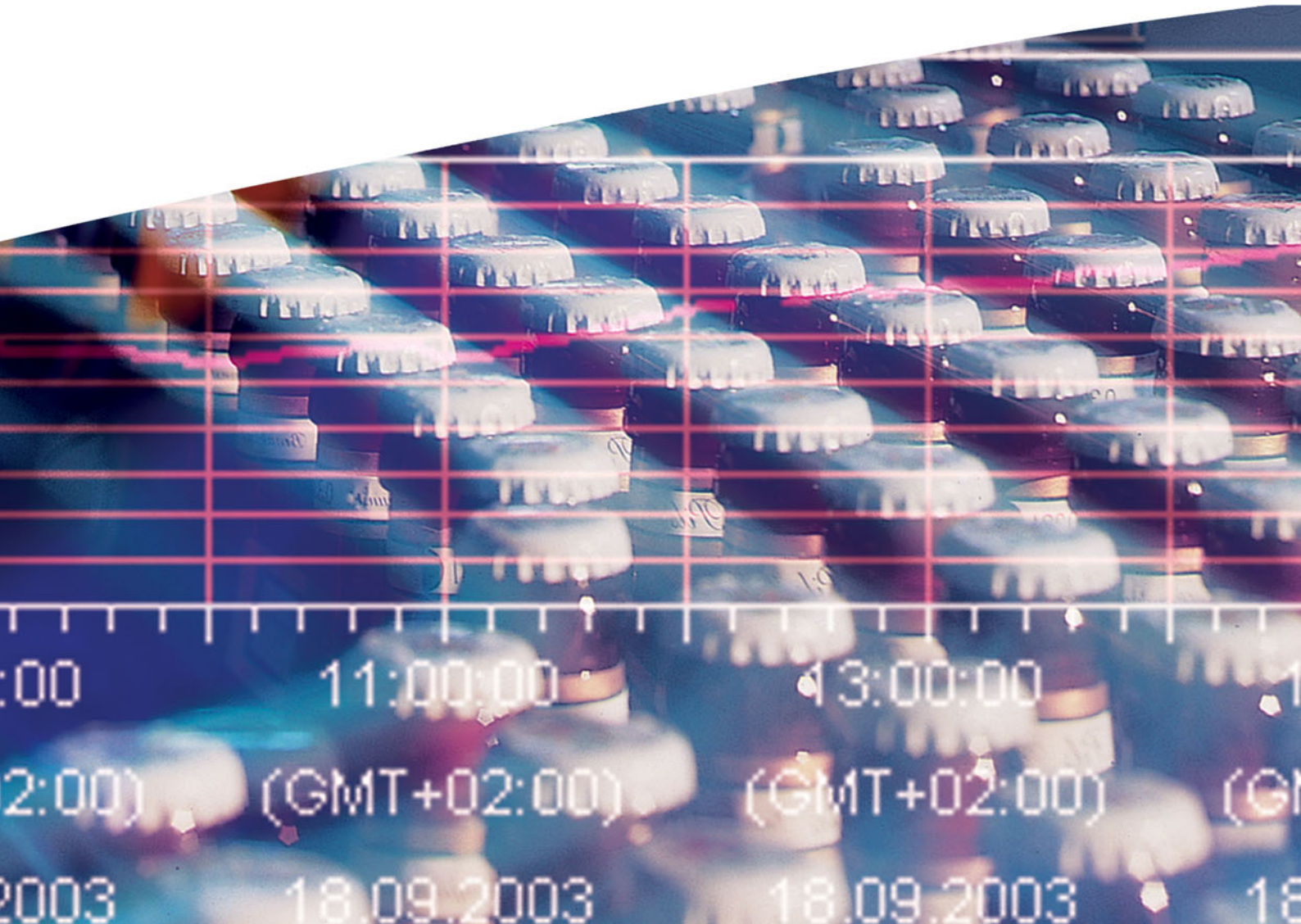
FDA-compliant data recording with the paperless recorder JUMO LOGOSCREEN es

Helmut Lysniak



JUMO GmbH & Co. KG
Moritz-Juchheim-Straße 1
D-36039 Fulda, Germany
Phone: +49 661 6003-0
Fax: +49 661 6003-500
e-mail: mail@jumo.net
Internet: www.jumo.net

Part Number: 00417087
Book Number: FAS 626
Print date: 10.03

Contents

1 Preface

Records in electronic form

LOGOSCREEN es

Manufacturers of pharmaceutical products must provide formal and systematic proof to national and international control agencies that their production system manufactures products that fulfill the quality and specification requirements on a reliable and lasting basis.

The Code of Federal Regulations 21 CFR Part 11 that was passed by the American FDA (Food and Drug Administration) in August 1997 makes it possible for records to be created, stored and evaluated in electronic form.

The paperless recorder “JUMO LOGOSCREEN es” presents, in conjunction with its PC software components, a closed system for the electronic acquisition, storage and archiving of processed data, that conforms to the requirements of 21 CFR Part 11.

The suitability of the system with regard to FDA requirements has been described in detail in the “JUMO White Paper”, Edition September 2002.

The product description of the “JUMO LOGOSCREEN es” illustrates the security and operating concepts behind the system, and the results that can be achieved by JUMO in the course of validation of a system. It is intended to serve as an introduction to the system, and not as a formal technical document.

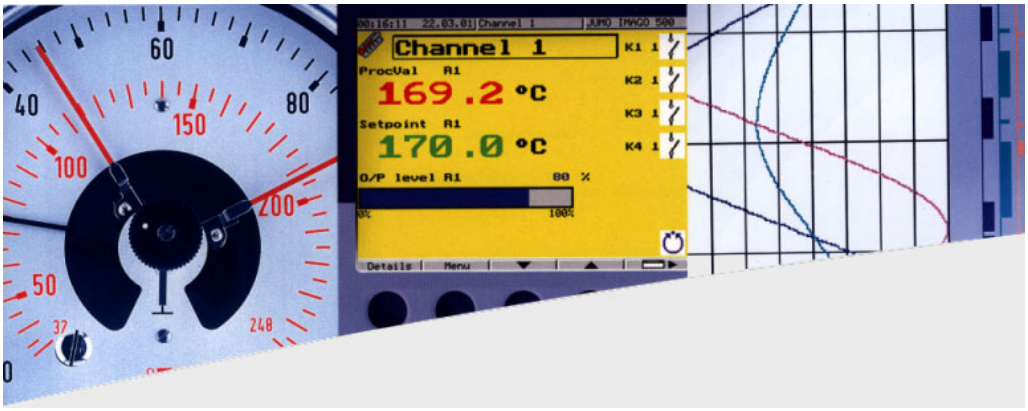
Helmut Lysniak

JUMO GmbH & Co. KG, Fulda, Germany

Success is an obligation

Instruments and systems from JUMO are at work on all five continents. They measure, control and record physical parameters in an extraordinarily wide range of industries. User-friendly and reliable, in every quantity and version that is asked for. And always with the guarantee of perfect quality and comprehensive service.

Supported by highly qualified employees and the most modern technology, JUMO has made a name for itself in global markets through its products and services.



Certified quality

In order to be able to back up our own claims and expectations in documented and testable form at any time, we apply a rigorous management system throughout all parts of the company, combining quality, environmental protection and workplace safety. All procedures in the various departments of our company are documented in detail, and continually monitored through internal and external audits. The most modern test systems support the production processes from reception of raw materials and components through to scrapping and disposal. Our certificates in accordance with EN ISO 9000 and EN ISO 14001 confirm that our expectations have been fulfilled. Quality as a way of life.


ZERTIFIKAT

DQS Deutsche Gesellschaft zur Zertifizierung von Managementsystemen mbH

JUMO Meß- und Regeltechnik M.K. Juchheim GmbH & Co

Umweltmanagementsystem

DIN EN ISO 14001


ZERTIFIKAT

DQS Deutsche Gesellschaft zur Zertifizierung von Managementsystemen mbH

JUMO Meß- und Regeltechnik M.K. Juchheim GmbH & Co

Qualitätsmanagementsystem

DIN EN ISO 9001

LOGOSCREEN es

FDA-compliant data recording
with the paperless recorder
JUMO LOGOSCREEN es

3 Requirements for the System Owner

System Owner

The operator of the installation (System Owner) requires that GMP-relevant data in electronic form is

- acquired
- electronically signed,
- saved
- evaluated and/or
- presented to the FDA for evaluation.

GMP

GMP (Good Manufacturing Practice) is the collection of rules to ensure good practice in manufacture.

GMP data

GMP data are data that arise during manufacture, checking, packing, warehousing and distribution of a product, and which

- directly affect the quality of a product
- form part of record documentation, and
- can be inspected by the appropriate authorities.

Electronic records

The term “electronic record” designates any combination of text, graphics, data, audio or visual material, and other representations of information in digital form, that can be created, altered, maintained, archived, retrieved or distributed by means of a computer system.

Electronic records as understood by 21 CFR Part 11:
- are GMP-relevant
- are electronically generated
- are stored on a non-volatile medium
- can be accessed and interpreted by technical means, and
- have been created after August 20th 1997.

Electronic signature

An electronic signature binds the measurement data acquired by the paperless recorder to a signature.

An electronic signature is a computer-generated symbol or combination of symbols that is executed, adopted or authorized by a person to be the legally binding equivalent of that person’s handwritten signature.

An electronic signature includes:
- the name of the signatory
- date and time of execution of the signature, and
- the implication (significance) of the signature (e.g. checking, approval ...).

4 FDA 21 CFR Part 11

FDA (Food & Drug Administration) is the American federal health authority.

21 CFR Part 11

This describes the FDA requirements for the electronic recording of data (electronic records), access control and the execution of electronic signatures.

The FDA regulations define the conditions under which the authorities consider electronic records and electronic signatures to be trustworthy, reliable, and in general of equal validity in place of paper records and handwritten signatures. To this end, it is vital that these electronic records are created, altered, maintained, archived, retrieved and transmitted in accordance with the regulations laid down by the authorities.

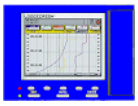
The FDA requires the proof of
- data security
- data integrity
- integrity of the audit trail, and
- legally binding signatures that are proof against forgery.

White Paper

The company's position with regard to fulfillment of the requirements of 21 CFR Part 11 by the JUMO LOGOSCREEN es is presented in the JUMO White Paper (TN 00409194).

5.1 Symbols used

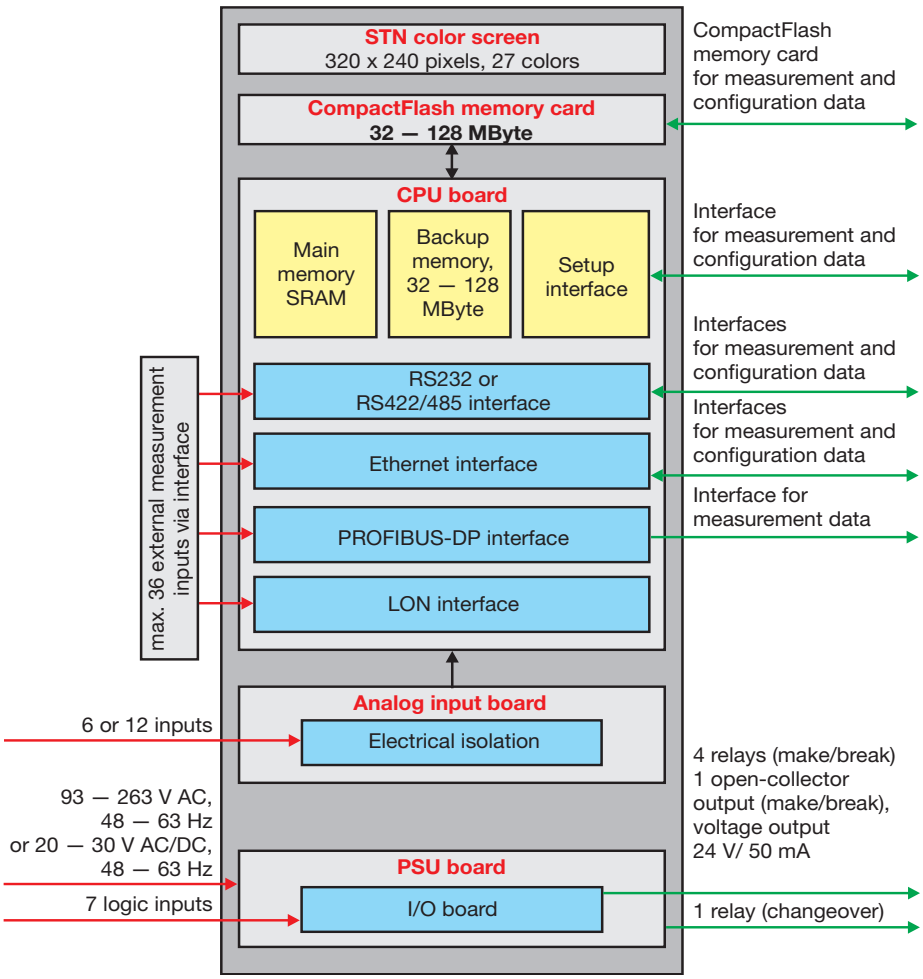
Usage

Symbol	Description	Location
	JUMO LOGOSCREEN es	- Device
	Setup software	- Device
	PC Evaluation software (PCA3000)	- PC
	PCA Communications software (PCC)	- PC
	Security Manager	- Device - PC
	Audit Trail Manager	- Device - PC
	System Owner	
	Administrator	
	User	
	Inspector	

5.2 System components

5.2.1 Hardware

Block diagram



Details of the measurement inputs

6 or 12 internal universal measurement inputs

The measurement inputs are implemented on two analog input boards which are built into the instrument (referred to as device in a software context).

24 external universal measurement inputs via mTRON modules (LON)

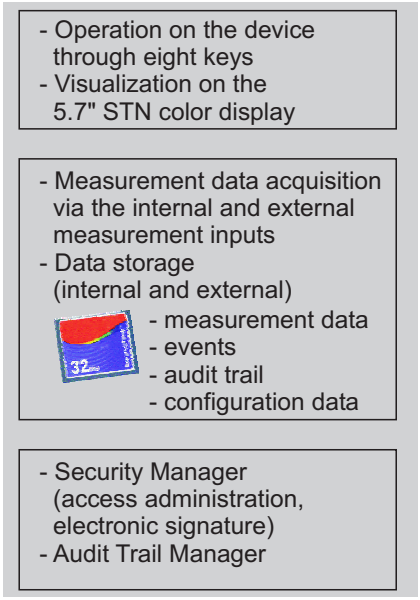
In addition to the 6 or 12 internal universal measurement inputs, up to 24 external measurement inputs can be connected to the paperless recorder through the JUMO mTRON automation system.

36 external universal measurement inputs via serial interface, Ethernet, or PROFIBUS-DP

If the paperless recorder is operated without using internal measurement inputs, then up to 36 inputs can be connected via an interface. The number of external measurement inputs is automatically reduced when internal inputs are used.

5.2.2 Device software

Block diagram



Visualization

Possible presentation modes:
- vertical diagram
- horizontal diagram
- evaluation of stored measurement data
- bar graph display
- numerical display (single or multi-channel)
- reports
- batch documentation
- event list, and
- audit trail

Data storage

The data are stored in the paperless recorder in an unpublished binary format. This is necessary to ensure that the data are tamper-proof.

Data security

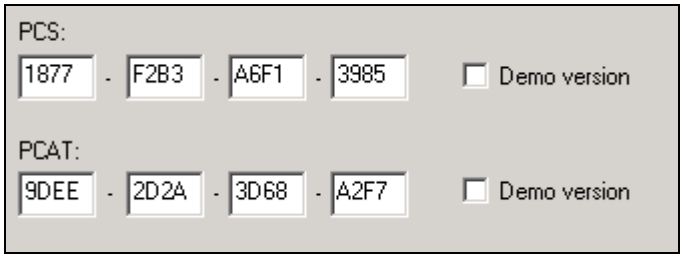
We ensure that the data format for the paperless recorder will not be altered in future.

External data storage

Concerning the problems of external data storage, we are of the opinion that long-term storage of data on optical media (CD, DVD) is reliable. We reckon that the data stored on such media will still be readable 20 years from now.

5.2.3 PC software

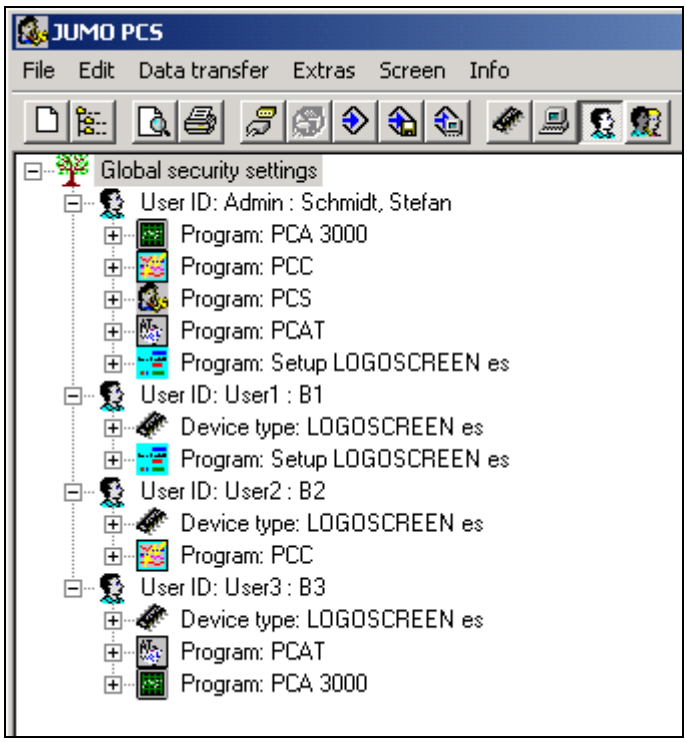
Administrator components



PC Security Manager software

This software is only accessible for administrators.

The PC Security Manager software (PCS) is used by the administrator to configure the system, by setting up user lists and assigning rights to the devices and PC programs to the users included in these lists.



PC Audit Trail Manager software

The PC Audit Trail Manager software (PCAT) is a PC program for the visualization of audit trail entries.

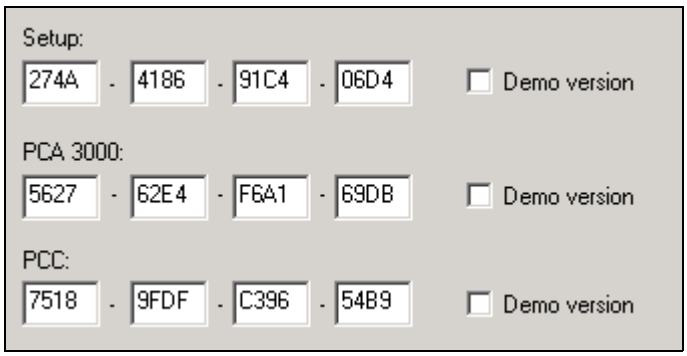
All changes in the PC software components and the devices are detected and recorded in the audit trail.

Audit trail records cannot be altered or deleted, and are inseparably linked to the electronic records.

Device audit trail data are not shown in PCAT, only in PCA3000.

All PC software components have an integral Audit Trail tool that creates the entries (independently of the Manager software).

User components



Setup software

The Setup software is a configuration software for project planning, commissioning and diagnosis.

PC Evaluation software

The PC Evaluation software (PCA3000) is used for archiving and evaluating data (including device audit trail data).

An electronic signature can be attached to the archived data in the software.

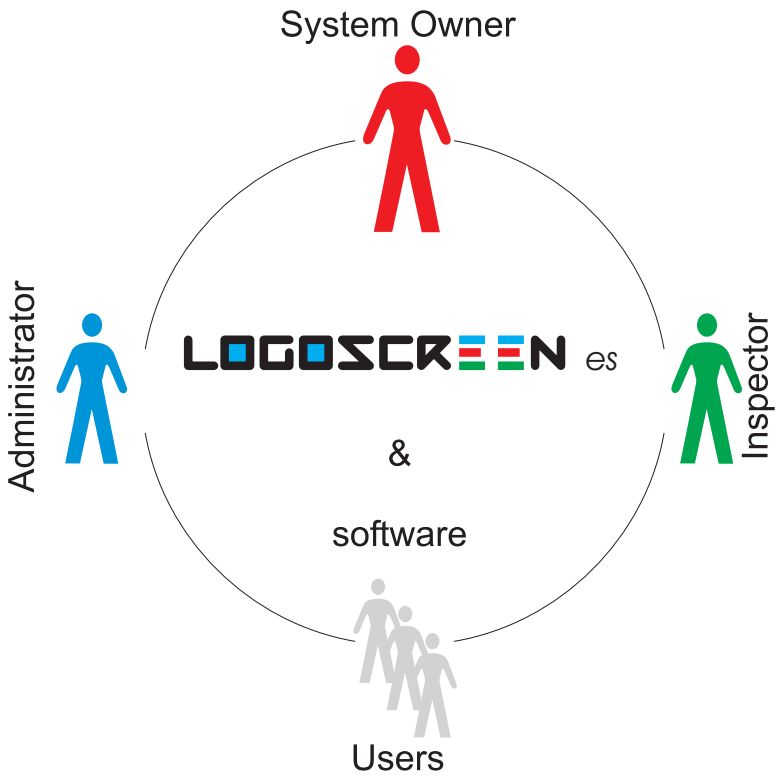
The software is freely available in read-only form on the Internet, for purposes of FDA inspection.

PCA Communications software

The PCA Communications software (PCC) manages the data transfer of process data from the paperless recorder to the PC, via a serial interface (cable or modem) and Ethernet (TCP/IP).

6.1 Responsibilities

Persons (groups) concerned



Tasks

System Owner

validates his system and maintains it in the validated condition

Users

use the system in accordance with the rights that have been assigned to them

Administrator

assigns access rights (authorizations) for the system components

Inspector

checks the process data that have been saved

Validation

Validation is a documented proof that a defined process produces a product that fulfills the quality and specification requirements on a reliable and lasting basis with a very high probability.

6 Security concept

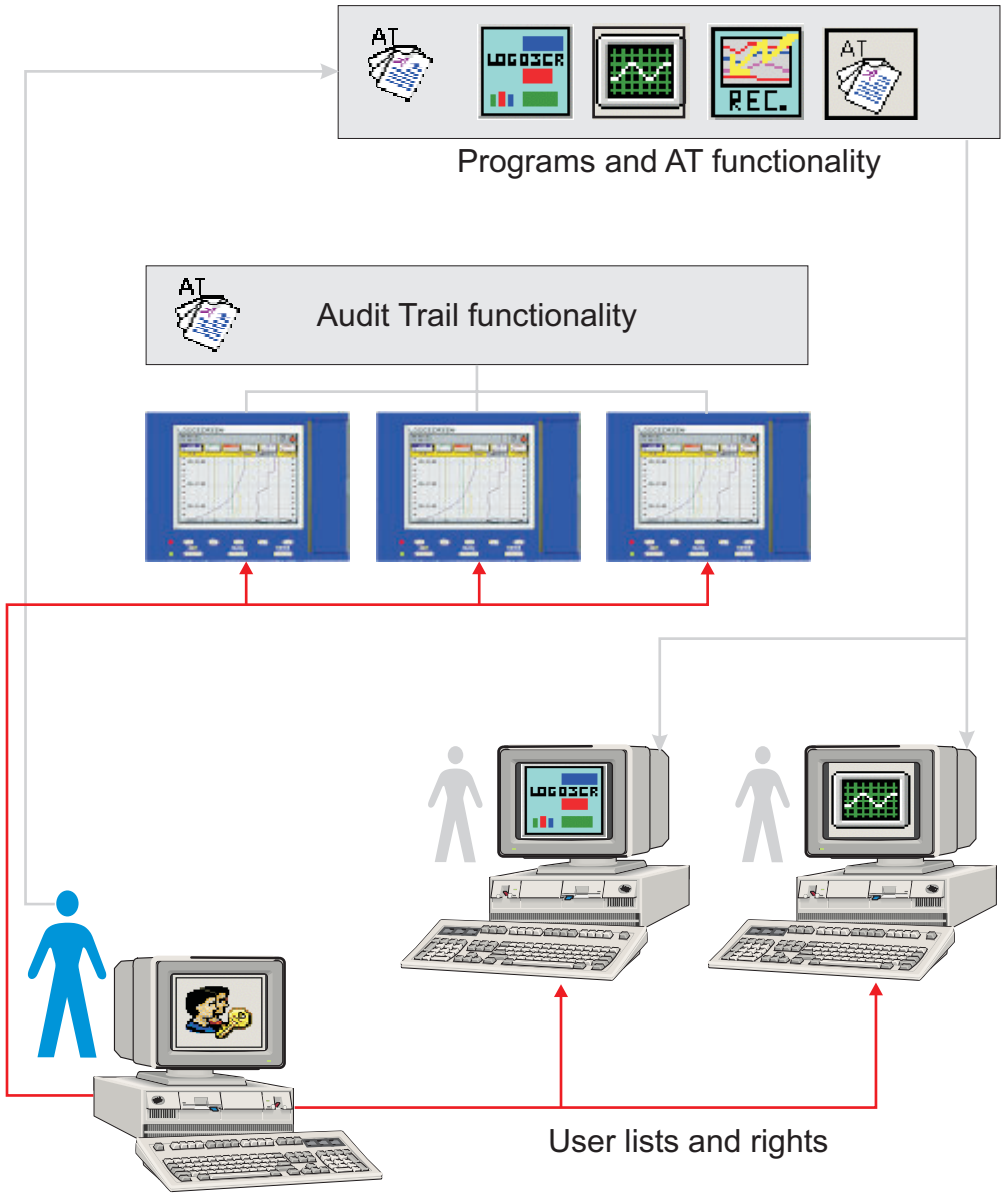
6.2 System acces (Security Manager)

A precondition for access to the system (paperless recorder and PC software components) is that the system components have been configured by an administrator. This configuration can only be performed through the PC Security Manager software.

The administrator sets up user lists and assigns rights to the devices and PC programs to the users included in these lists.

A user list contains two identification components (ID and password) for each user, and the user rights. User lists ensure that the system can only be accessed by authorized persons.

The number of users in the PC user lists is not limited. A maximum of 30 users can be managed in one device.



Paperless recorder	The user lists can be transferred to the paperless recorder via the interface or a CompactFlash card.
PC software components	The user lists can be transferred to the user PCs via the network or any suitable storage medium.
Rights	Rights are assigned solely by the administrator, with the help of the PC Security Manager software. A distinction is made between paperless recorder rights and PC software rights. Rights can be variously defined for individual users (administrator: all rights, user: limited rights). User profiles can be predefined, to simplify the process of assigning rights.

6 Security concept

6.3 Audit Trail

The system makes use of audit trails that are secure, computer-controlled, and provided with a time-stamp. In this way, an independent record is kept of the date and time of any entries or actions undertaken by operating personnel that could generate, alter or delete any electronic records.
The system ensures that entries already made cannot be overwritten or masked.

The audit trail must be preserved for the same period of time that applies to the electronic records concerned. Audit trails are to be used for documents that fall under these regulations, when data are recorded, updated, deleted or archived in an official database or data repository.

Audit trails are generated on screen as well as for every PC software component.

PC audit trail entries are visualized through the PC Audit Trail Manager software. Audit trail entries for devices are visualized throught the PC Evaluation software (PCA3000).

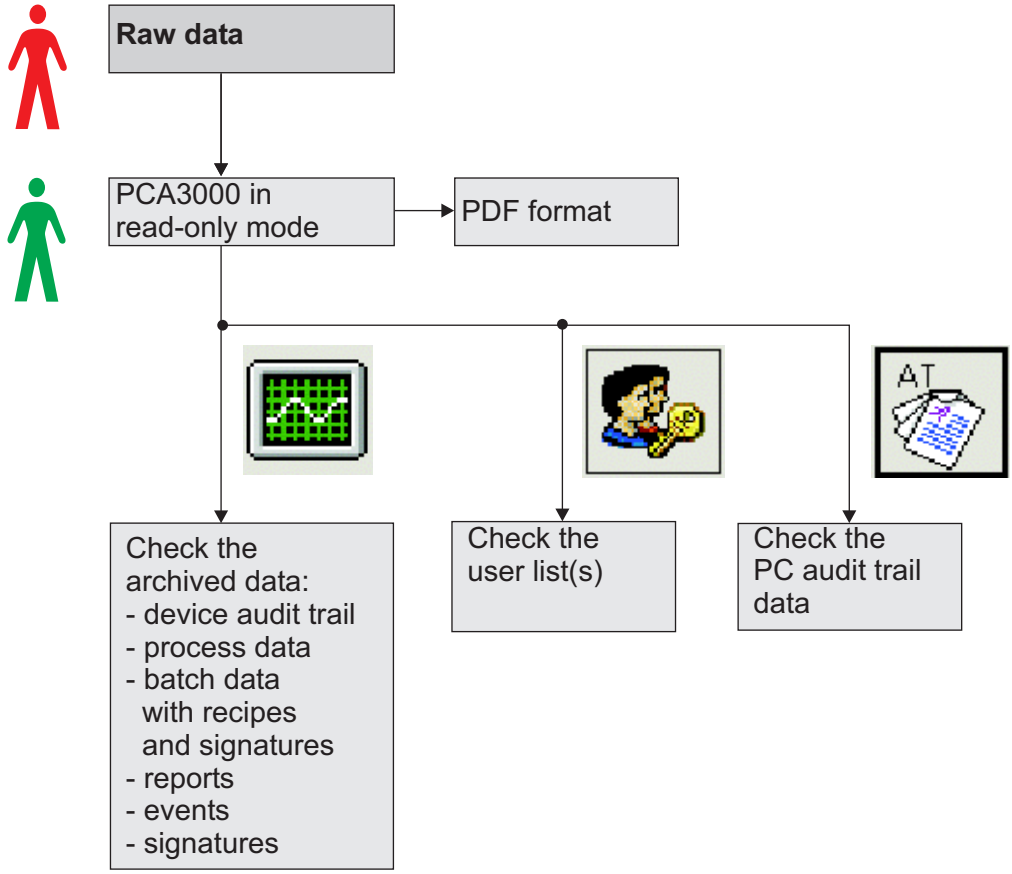
6.4 Checks

Data

Process data are stored in the recorder and the PC archive in an unpublished proprietary format (a binary data format).

It is assured that, from the records that are generated within the system, accurate and complete copies can be made in a form that is legible for persons as well as in an electronic form, for the purposes of inspection, checking and copying by the authorities.

Data can therefore be visualized through two options:
- as raw data, which can be read by the PC software PCA3000 in read-only mode
- as PDF files, which can be read with the aid of Acrobat Reader.



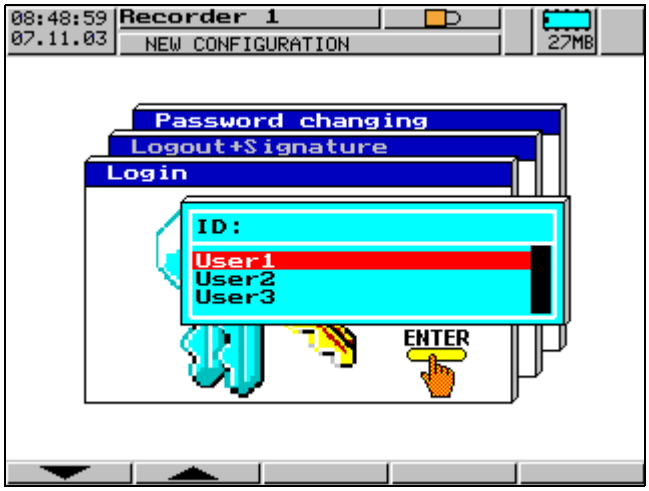
☞ The Adobe Acrobat software or a comparable PDF printer driver is required for the generation of a PDF file.

7 Operating concept

7.1 Device

7.1.1 Log-in and log-out

Log-in through user list



Double log-in

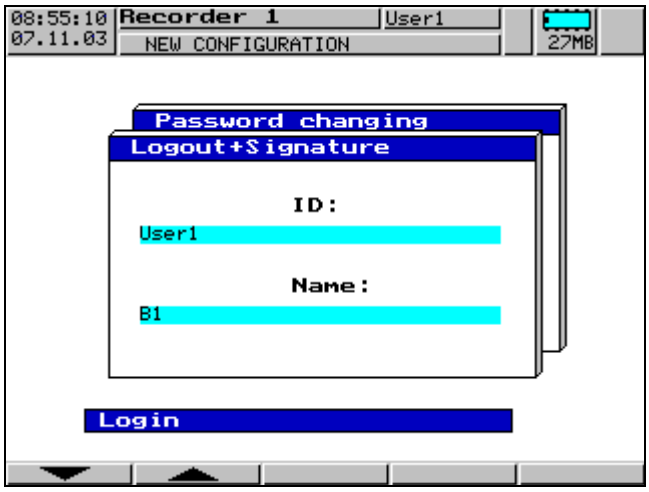
☞ If a second user logs in to a device where a user is already logged in, then the first user is automatically logged out.

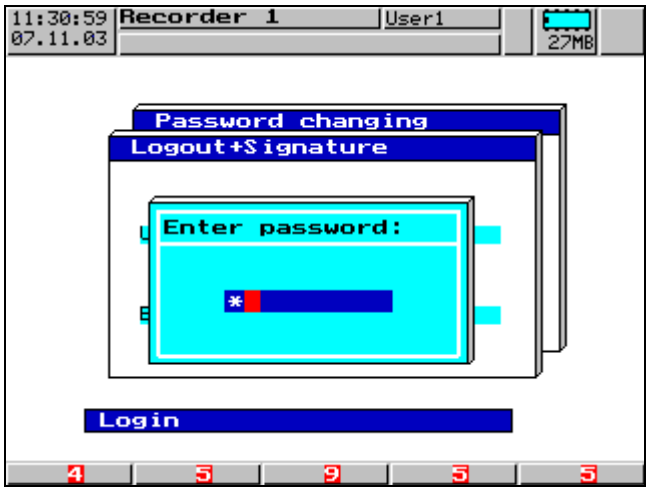
Incorrect attempts

☞ If a user repeatedly provides an incorrect password, then access will automatically be barred for this user. The acceptable frequency of incorrect attempts is defined by the administrator, in the Security Manager software.

Log-out

The log-out from the paperless recorder is defined by the password rules in the PC Security Manager software. Here it can be defined whether or not an electronic signature has to be executed for log-out.

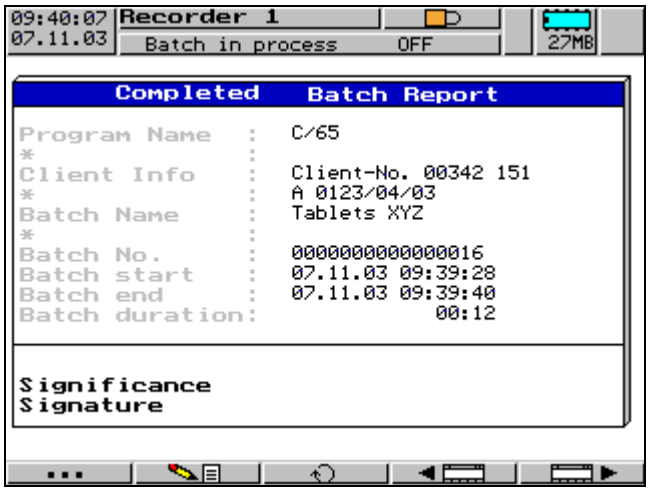


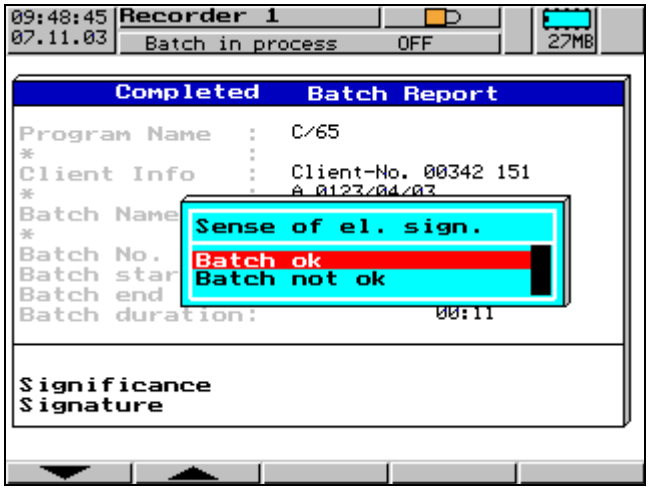


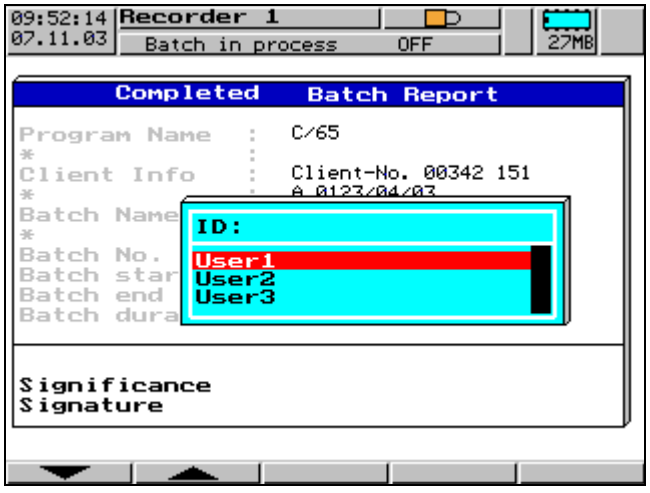
7.1.2 Electronic signature at the device

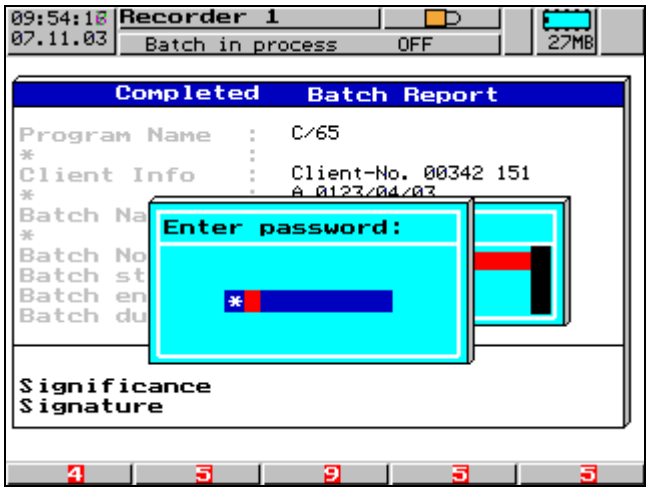
An electronic signature can be executed for a completed batch process, or when logging out from a device.

Signing a batch

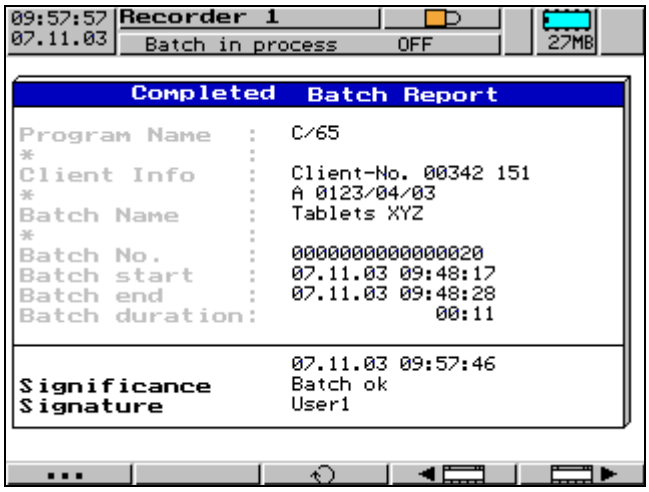







09:54:18
07.11.03
Recorder 1
Batch in process
OFF
27MB
Completed Batch Report
Program Name : C/65
Client Info : Client-No. 00342 151
Enter password:
Significance
Signature


09:55:49
07.11.03
Recorder 1
Batch in process
OFF
27MB
Completed Batch Report
Program Name : C/65
Please confirm!
This signature is legally binding like a handwritten signature.
Abort: EXIT
OK: ENTER
Significance
Signature


09:57:57
07.11.03
Recorder 1
Batch in process
OFF
27MB
Completed Batch Report
Program Name : C/65
Client Info : Client-No. 00342 151
A 0123/04/03
Batch Name : Tablets XYZ
Batch No. : 0000000000000020
Batch start : 07.11.03 09:48:17
Batch end : 07.11.03 09:48:28
Batch duration: 00:11
07.11.03 09:57:46
Significance Batch ok
Signature User1

7.1.3 Batch report

Definition

A batch report is unambiguously defined by a start signal and a stop signal.

Batch data

Batch data are registered in a batch report. The layout of the report can be arranged by the operator, on the recorder, or with the help of the Setup program.

Up to 10 freely configurable lines of text are available for a description of the batch process, with two lines of text for the electronic signature and its significance. Each line consists of two text fields.

- Text field 1 defines which general batch data are to be documented.
- Text field 2 defines the specific batch-related text.

Example

Line	Text field 1	Text field 2
1	Program name	C/65
2		
3	Customer info:	Cust. No. 00342 150
4		
5	Batch name	A 0123/03/03
6		Tablets XYZ
7	Batch number	12345
8	Batch start	14.03.2003 07:00:00
9	Batch end	14.03.2003 16:00:00
10	Batch duration	09:00:00
11	Significance	Batch OK
12	Signature	User1

The batch-related texts in text field 2 can be generated by:

- fixed texts (direct entry)
- the text list (selection from preconfigured texts)
- binary-linked texts (selection from the text list, according to the states of the logic inputs)
- the interface
- the batch number (which is automatically incremented),
- the batch start (date and time)
- the batch end (date and time)
- the batch duration
- the significance (freely selected, or selection from a text list)
- the signature (ID of the signatory).

7.2 PC software

The components

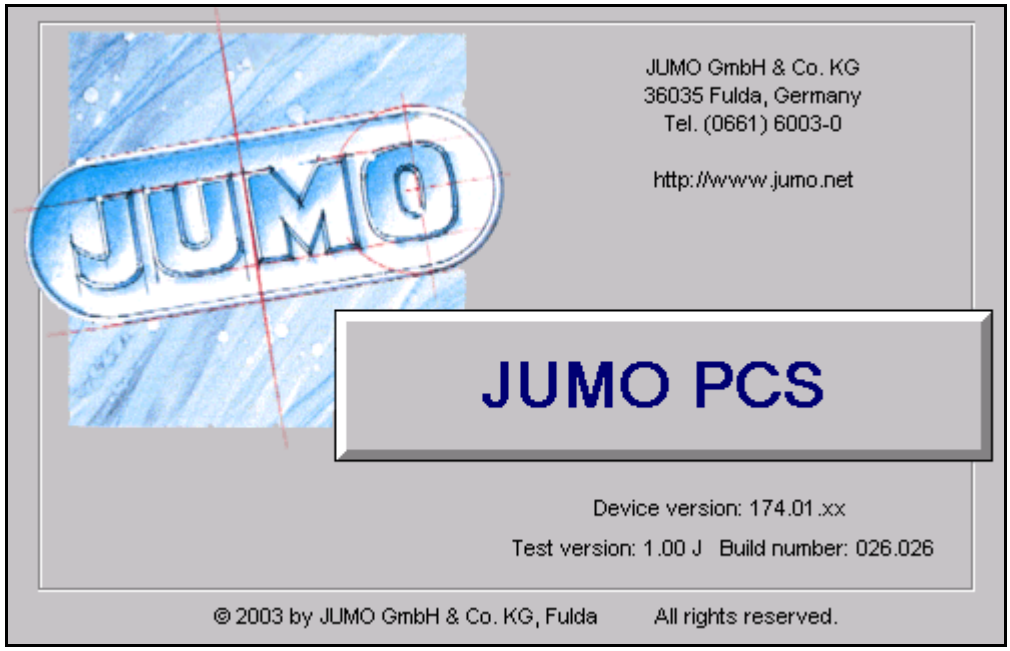
The JUMO PC software package comprises five components.
- Setup software
- PC Evaluation software (PCA3000)
- PC Communications software (PCC)
- PC Security Manager software (PCS)
- PC Audit Trail Manager software (PCAT)

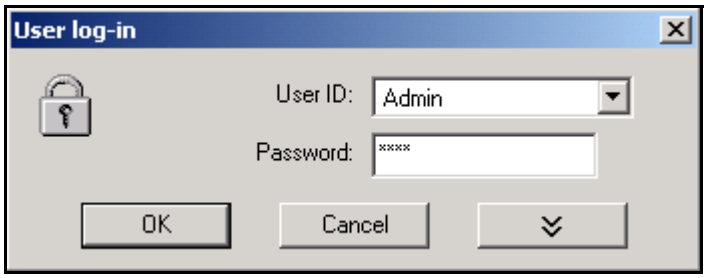
All the software components include the same security-relevant features as the paperless recorder (user list and audit trail tool).

Security Manager software

Rights for the individual users and their access to the individual software components are assigned by the administrator, with the help of the Security Manager software.

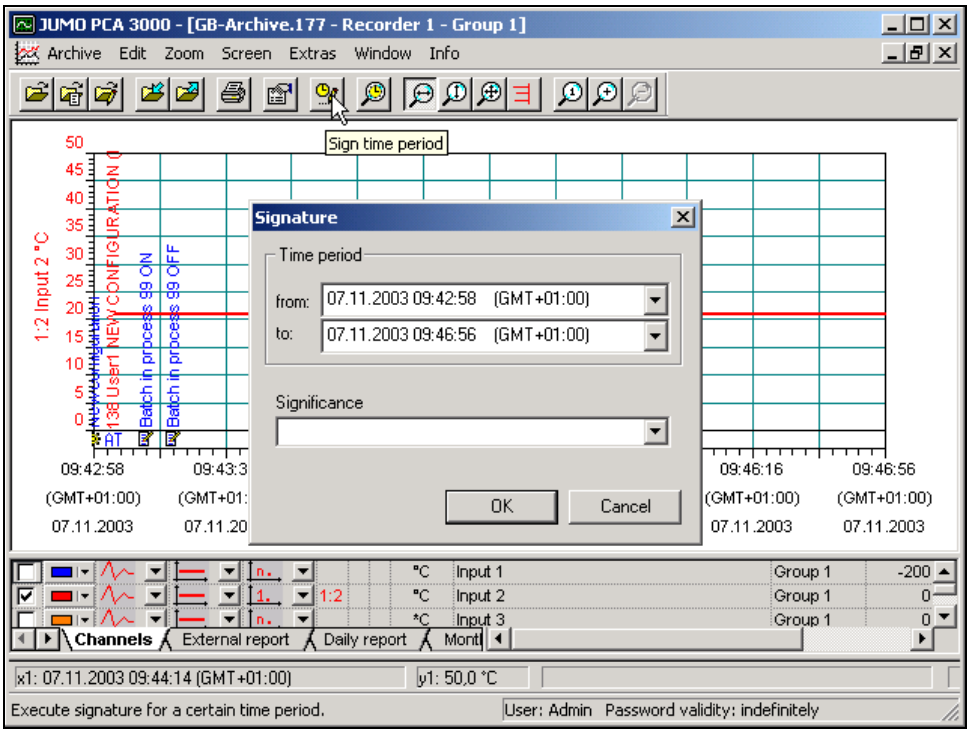
The software components can only be used when the user name (ID) and password are entered.



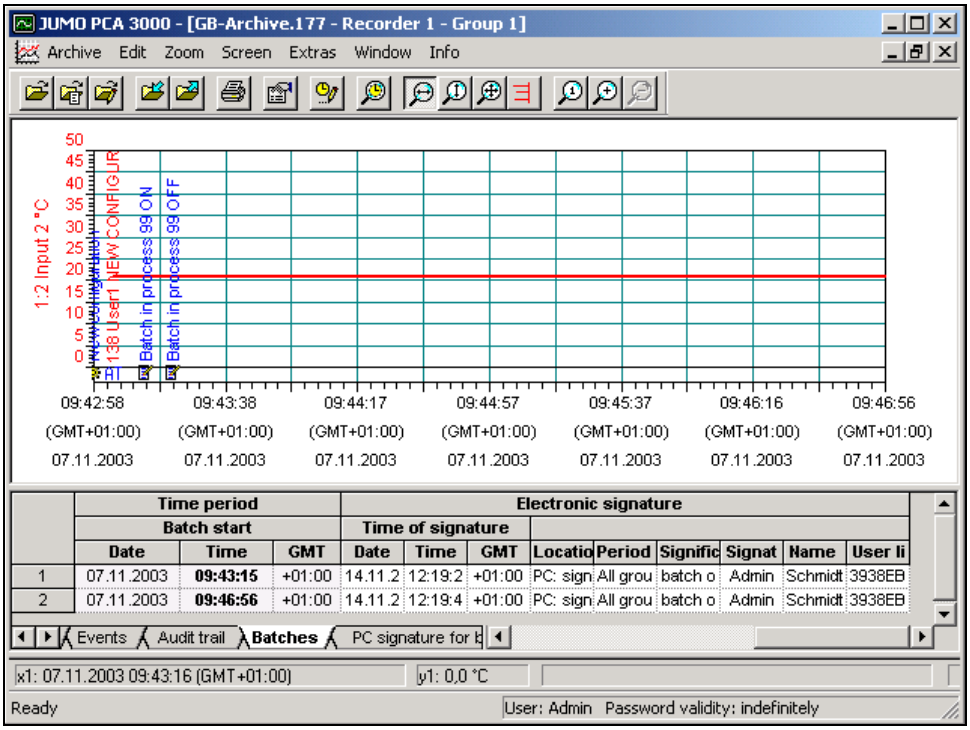


7.2.1 Electronic signature at the PC

Archived data can have an electronic signature attached, through the PC Evaluation software (PCA3000) .



The electronic signature is automatically recorded in the audit trail of the PCA3000 software. This signature cannot be erased. It is indissolubly linked to the data of the time period for which the signature has been executed.



8.1 IQ – Installation Qualification

Installation Qualification

- Person responsible: System Owner
- Support: JUMO product specialist

The IQ is carried out on the occasion when the equipment is installed. The following are checked: that the delivered products are correct and complete, including the documentation, that the equipment and the PC software have been correctly installed, and that the equipment and PC software functions operate correctly.

8.2 OQ – Operation Qualification

Operation Qualification

- Person responsible: System Owner
- Support: JUMO product specialist

The OQ is carried out for the first time during the commissioning phase, following the IQ. The OQ confirms that all the components belonging to the system being qualified perform faultlessly within their specifications.

The OQ is repeated by the System Owner at fixed intervals.

8.3 PQ – Performance Qualification

Performance Qualification

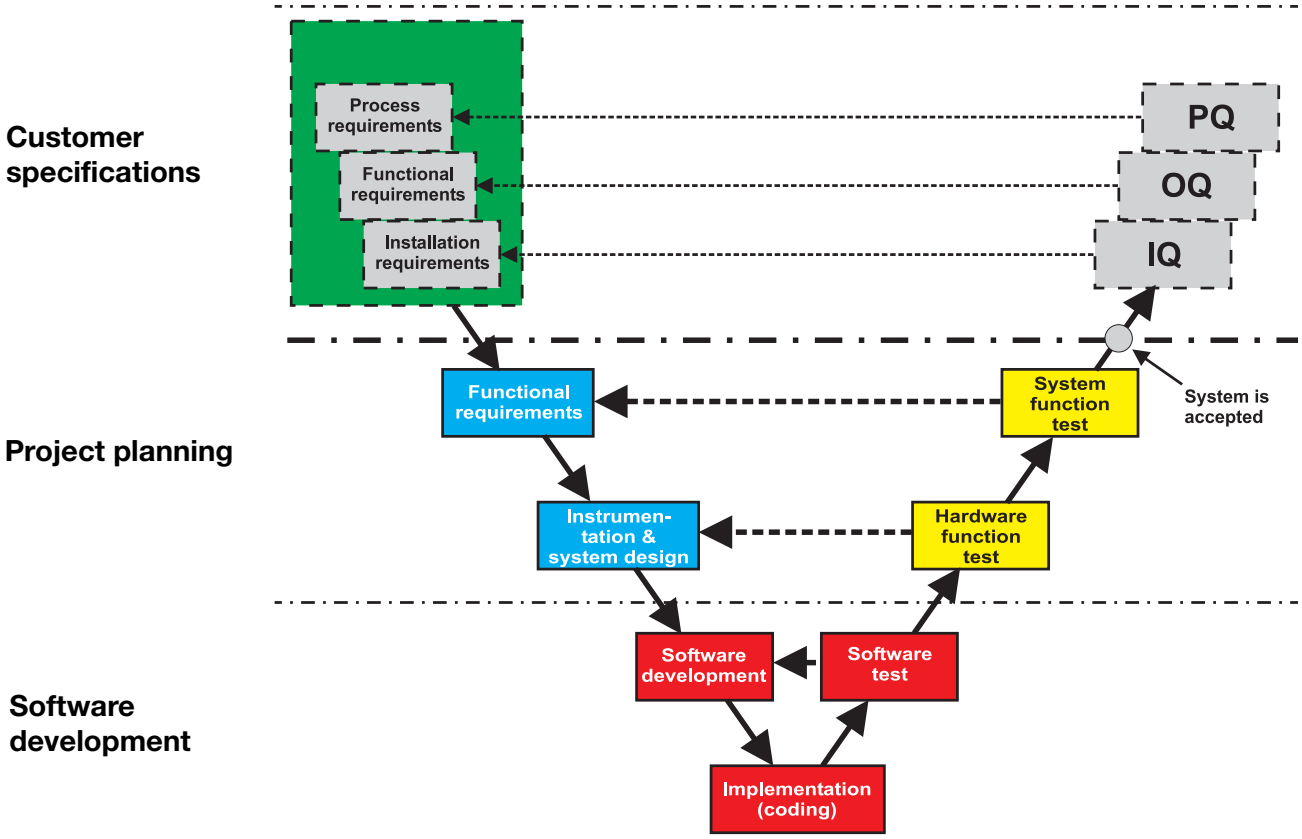
- Person responsible: System Owner

The PQ is carried out periodically by the System Owner during routine operation, according to the description of the task laid down by the System Owner, and confirms that the equipment is suitable for the task to be performed. All necessary documents and process instructions required for the validation status must be available.

8 Qualification

8.4 The V model

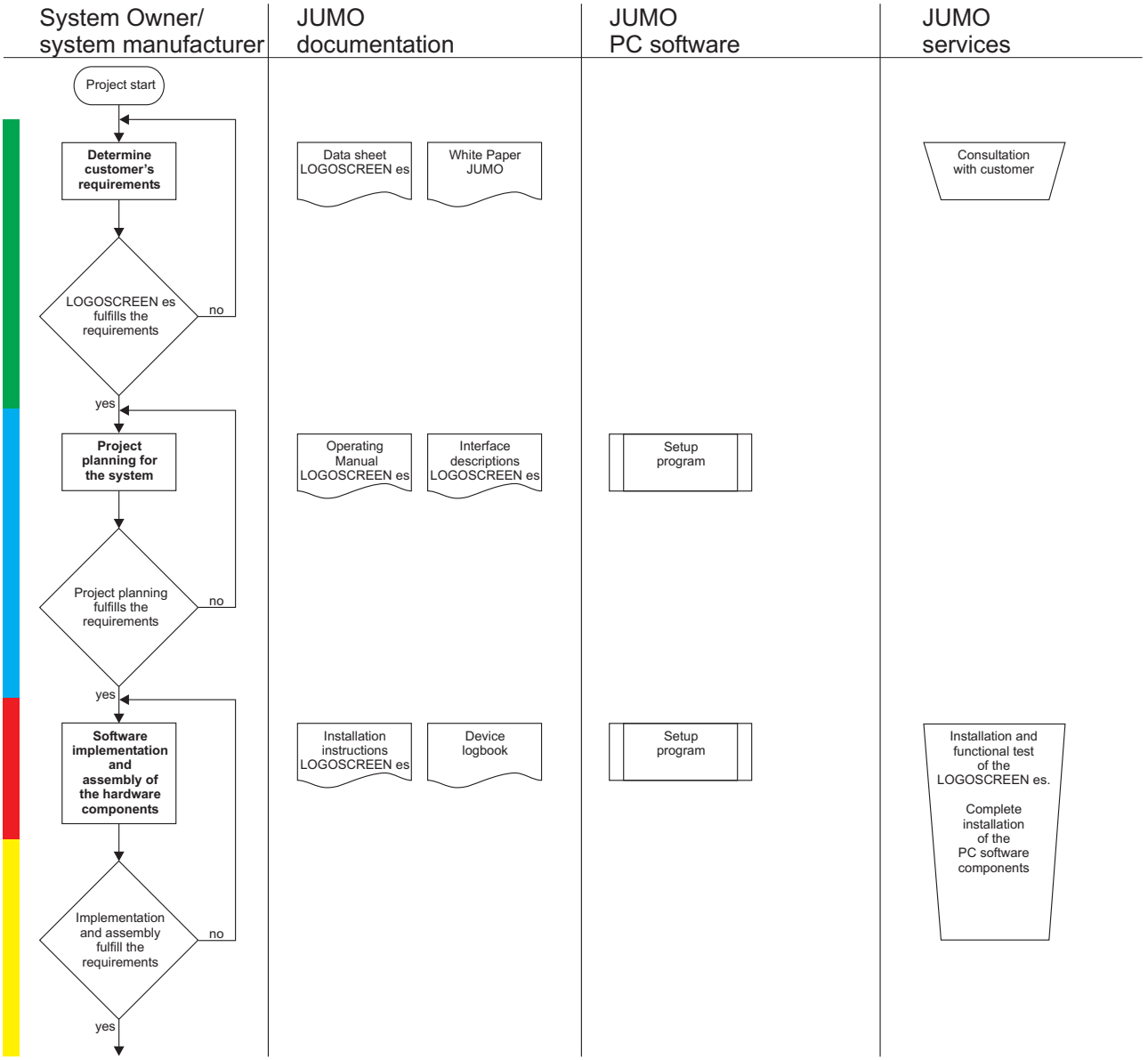
The V model is a phase model. It defines activities, development phases, documents to be supplied, as well as the acceptance and final criteria for every phase. The aim is the validation of a production process.



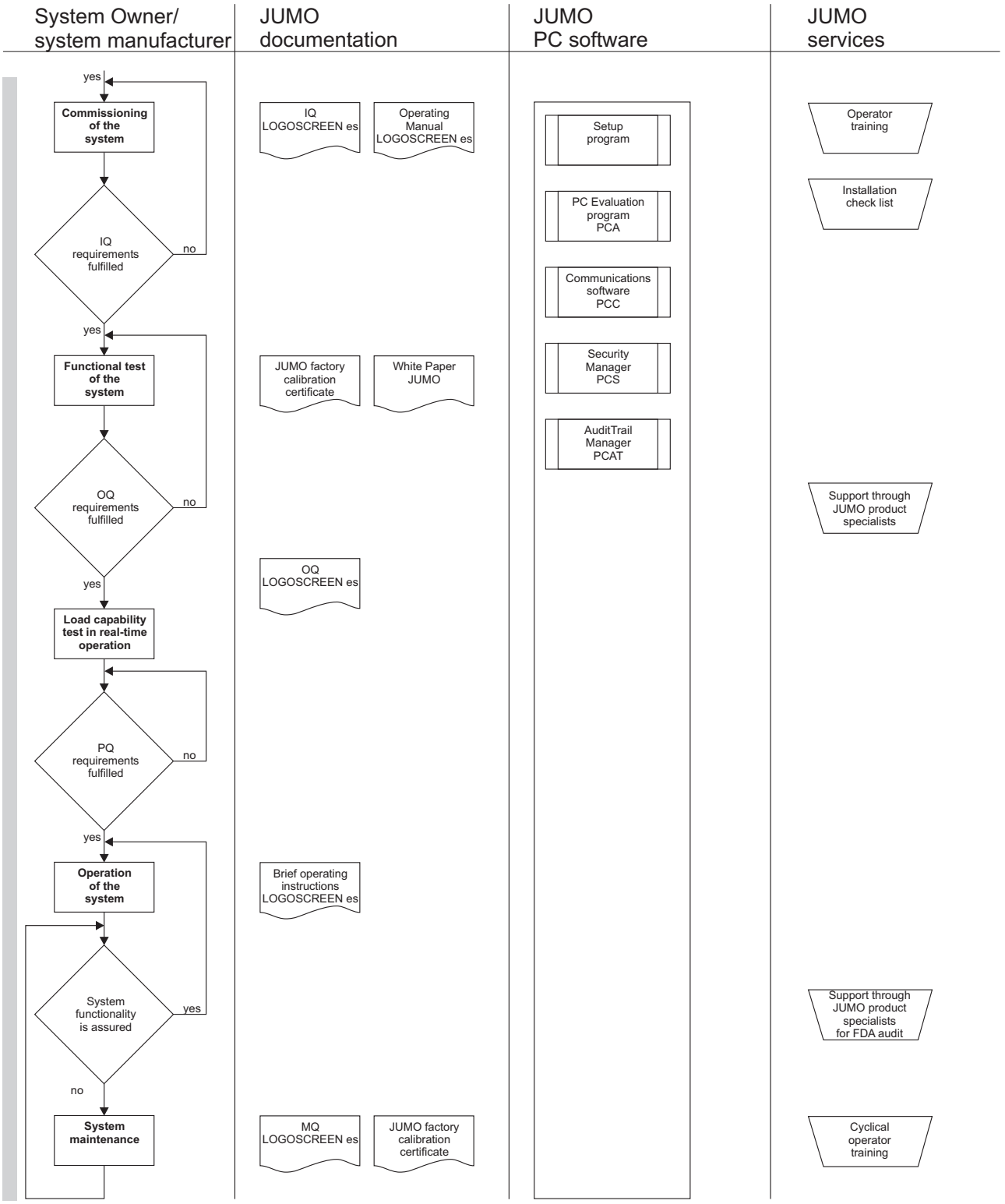
The evaluation of the quality of a system can be made on the basis of the orderly and systematic process by which it is constructed. One recognized method of achieving this is to proceed according to the V model.

8.5 Sequential plan ...

... for implementing the paperless recorder “JUMO LOGOSCREEN es” in a production system that is to be validated.



8 Qualification



FDA-compliant data recording

- The paperless recorder and its associated PC software components form a closed system for the electronic acquisition, storage and archiving of measurement data that fulfills the requirements of 21 CFR Part 11 in respect of the security of electronic records and electronic signatures.
- Electronic records are created in the instrument in such a way that they are tamper-proof and can be sealed by an electronic signature.
- The electronic signature in the paperless recorder and the PCA3000 is not based on biometrics. It contains two different identification components (a user ID and a password).
- It is ensured that an electronic signature can only be executed by the proper user.

  Signed electronic records include the following items:
  - first name and surname of the signatory
  - date and time when the signature was executed
  - the interpretation and significance of the signature (e.g. checking, approval ...).
- Safety measures have been implemented that immediately register any attempts at manipulation or unauthorized access.
- Secure audit trails with a time-stamp are used, both in the paperless recorder and the PC software components, to make an independent record of the date and time of all entries and actions performed by the operating personnel that could generate, alter, or delete electronic records.
- JUMO sees itself as a service provider for the pharmaceutical industry, and thus offers the following service:
  - training of the operating personnel
  - cooperation in the generation of qualification documents, and
  - support for audits conducted by FDA inspectors.

JUMO

www.jumo.net