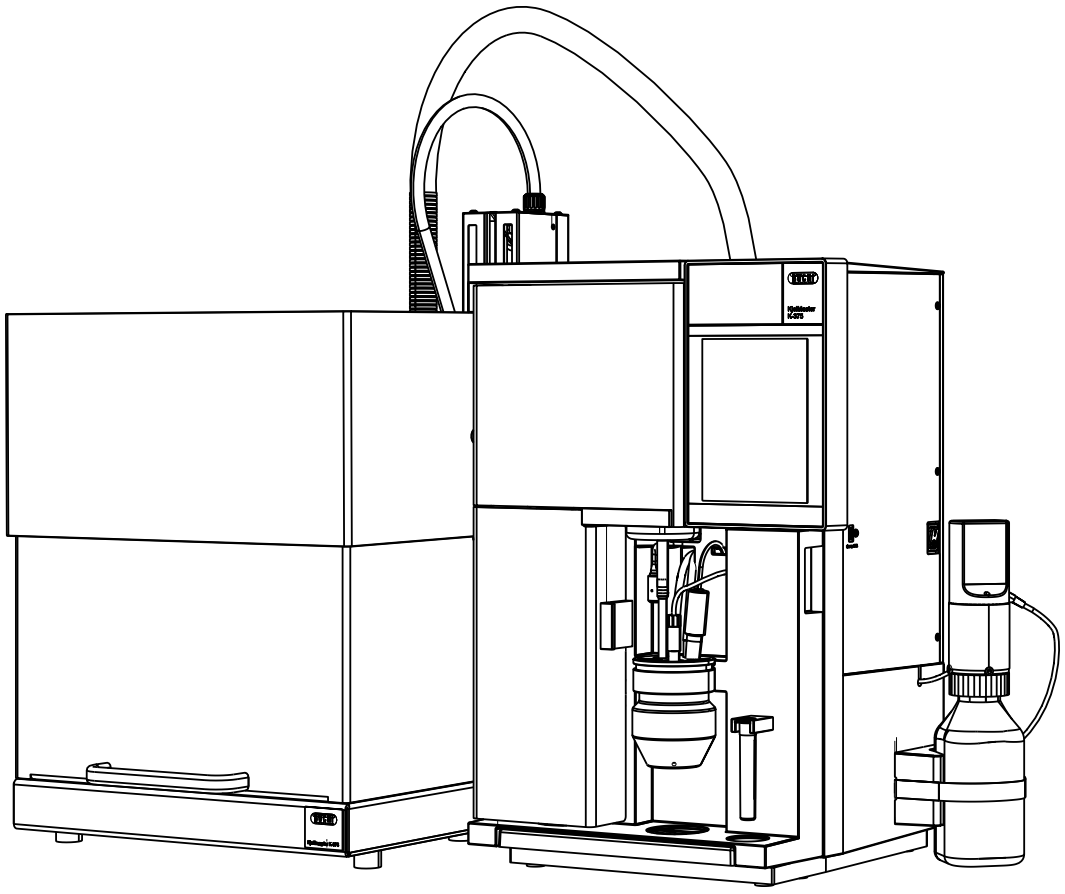
KjelMaster K-375
Manual – 21 CFR Part 11 Regulation



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1 About this document

The purpose of this document is to outline the responsibilities regarding the 21 CFR Part 11 regulation and inform KjelMaster K-375 users in regulated environments how the Pharma Package handles these requirements.

2 What is 21 CFR Part 11?

What is 21 CFR Part 11?

The Code of Federal Regulations Title 21 Part 11 of the U.S. Food and Drug Administration, known as 21 CFR Part 11, defines the requirements for using electronic records and electronic signatures on computerized systems and how this affects the setup and usage of it. The basic requirement forces computerized systems to ensure the integrity, reliability and trustworthiness of electronic records.

In addition, electronic signatures must be trustworthy and equivalent to handwritten signatures executed on paper records. Under the title 21 “Food and Drugs” in part 11 “Electronic records; electronic signatures” the regulation describes the following topics:

Subpart A – General Provisions

11.1 – 11.3 Scope. Implementation. Definitions.

Subpart B – Electronic Records

11.10 Controls for closed systems.

11.30 Controls for open systems.

11.50 Signature manifestations.

11.70 Signature/record linking.

Subpart C – Electronic Signatures

11.100 General requirements.

11.200 Electronic signature components and controls.

11.300 Controls for identification codes/passwords.

Subpart A explains the general provisions of the regulation whereas Subpart B and C take care of the relevant requirements for computerized systems. Because the KjelMaster K-375 is a computerized system, it must comply with those requirements. The table in Chapter 3 "KjelMaster K-375 Pharma Package solution for the 21 CFR Part 11 requirements", page 6 of this document, goes through all sections of the 21 CFR Part 11 topics and shows how the KjelMaster K-375 Pharma Package complies. Given that the KjelMaster K-375 with the Pharma Package will not be used as an open system, the section 11.30 of subpart B is not listed in the table.

3 KjelMaster K-375 Pharma Package solution for the 21 CFR Part 11 requirements

3.1 Subpart B: Electronic records

Compare the FDA requirements for electronic records with the KjelMaster K-375 features and find out how they comply.

Fully compliant: ✓ Cannot be solved from any instrument; owner company must ensure compliancy: ✓ Attention: ⚠

Reference section	21 CFR Part 11 Regulation Text (short description)	KjelMaster K-375 with Pharma Package	Conformity
B-11.10	Controls for open and closed systems	With the Pharma Package the KjelMaster K-375 can only be used as a closed system with dedicated security, user management and data tracking functions.	✓
(a)	Validation of systems	BUCHI offers extensive IQ/OQ procedures and documentation that follows GAMP guidelines to validate KjelMaster systems accordingly. Each device for the Kjeldahl process is delivered with conformity certificates.	✓
(b)	Generation of complete and audit ready records/copies	The KjelMaster K-375 can export and print copies of electronic records that preserve the content and meaning of the records in different formats (pdf and xml). All electronic records, or their copies, are human-readable.	✓
(c)	Protection and recoverability of records/copies	The KjelMaster K-375 offers backup procedures to save and restore electronic data. Due to limited instrument memory (1 GB) authorized personnel (Administrator) should delete electronic records and system event logs (audit-trail data) from time to time. An intelligent export logic takes care of retaining all system event logs along with the underlying data, therefore, all delete, export and other important user actions are recorded in the system event log (audit-trail) which makes the complete deletion process trackable for audits. Nevertheless, BUCHI advises some additional actions to consolidate compliancy, see: ⚠	✓

Reference section	21 CFR Part 11 Regulation Text (short description)	KjelMaster K-375 with Pharma Package	Conformity
(c)	Protection and recoverability of records/copies	BUCHI advises the definition of a SOP (Standard Operation Procedure) for archiving data and system event logs generated on the KjelMaster K-375. Our recommendation is to export/print the generated measurement data, electrode calibrations and system event logs to a read-only network folder. This should be done on a regular basis and before the data is deleted by authorized personnel (Administrator). In doing so you ensure compliancy and are prepared for any audits. This will ensure no down time of the KjelMaster K-375. See also Chapter 5 "User Management", page 13	
(d)	Limiting system access to authorized individuals	The KjelMaster K-375 restricts data access to unauthorized individuals (instrument login is only possible with a username and password). Moreover, the instrument can lockout a user after 10 minutes of inactivity (re-entry is possible with a valid username and password). The system has a password aging feature (a new password is required after 90 days) as well as access locking (user is locked out after three wrong login attempts). The given password must consist of at least 8 characters (including one special character, one capital letter, one small letter and one number) and is not reusable for 6 password cycles.	
(e)	Audit trail functionality	The KjelMaster K-375 comes with a system events log function. This function serves as an audit trail by tracking all quality relevant data automatically and respective to the user in a human-readable, exportable format. The system events log runs permanently and all entries are protected from changes by any user. An intelligent export logic retains all system event logs with all quality relevant data consistently. See also Chapter 7 "System events log (Audit-trail)", page 17	

Reference section	21 CFR Part 11 Regulation Text (short description)	KjelMaster K-375 with Pharma Package	Conformity
(f)	Operational sequences	The KjelMaster K-375 allows the programming and management of individual Kjeldahl (automation, distillation, titration) methods and measurement sequences. The instrument is delivered with ready-to-use method templates.	
(g)	Authority checks	The KjelMaster K-375 restricts access to unauthorized individuals (login with individual username and password). It supports three user levels (Administrator, Lab-Manager and Operator) and each user level has predefined rights. See table in Chapter 5 "User Management", page 13	
(h)	Device checks	To ensure the validity of data inputs/outputs, BUCHI offers IQ/OQ procedures. In addition, the instrument serial number of every KjelMaster K-375 is linked to printed and exported data.	
(i)	Training	The KjelMaster K-375 is delivered with user instruction manuals and dedicated user training. Training courses for all application fields and individual training courses can be arranged through BUCHI. Each of our distributors and sales reps are trained on the instrument.	
(j)	Establishment and adherence to given policies	If an electronic signature is used, then the instrument owner must have a policy in place in which the equality of handwritten and electronic signatures is made clear.	
(k)(1)(2)	Documentation control mechanisms	All KjelMaster K-375 related documents are available in electronic and printed format. They have a documented change history and are handled according to the ISO 9001:2015 Quality Management System.	

3.2 Subpart C: Electronic signatures

Compare the FDA requirements for electronic records with the KjelMaster K-375 features and find out how they comply.

Fully compliant: ✓ Cannot be solved from any instrument; owner company must ensure compliancy: ✓ Optional feature: ✓

Reference section	21 CFR Part 11 Regulation Text (short description)	KjelMaster K-375 with Pharma Package	Conformity
B-11.50 (a)	Signed electronic records shall contain information associated with the signing that clearly indicates all the following: 1. The printed name of the signer 2. The date and time when the signature was executed 3. The meaning (such as review, approval, responsibility, or authorship) associated with the signature.	Measurement results, measurement methods and all system event logs on the KjelMaster K-375 are automatically signed with user information: 1. Username (user definable) 2. Date and time of execution 3. User-level (Operator, Lab-Manager or Administrator) Only Administrators and Lab-Managers can approve measurement data – approvement is done during export/print of data from the KjelMaster K-375.	✓
(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).	The information mentioned in B-11.50 (a;1,2,3) can be displayed, printed and exported on the KjelMaster K-375 as a component of the electronic record. See also Chapter 6 "Electronic Signatures", page 16	✓
B-11.70	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.	Signatures are linked to their respective electronic records and prevented from falsification.	✓
C-11.100 (a)	Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.	Electronic signatures are uniquely assigned to a user (username and password). Existing users can be locked by authorized personnel (Administrator) to ensure usernames are not reused. In general, the instrument owner is responsible for ensuring that identification is not shared by anyone else.	✓

Reference section	21 CFR Part 11 Regulation Text (short description)	KjelMaster K-375 with Pharma Package	Conformity
(b)	Before an organization establishes, assigns, certifies, or otherwise sanctions an individual's electronic signature, or any element of such electronic signature, the organization shall verify the identity of the individual.	It is the responsibility of the instrument owner to verify the identity of all individuals who are working with the KjelMaster K-375.	
(c)(1)(2)	Persons using electronic signatures shall, prior to or at the time of such use, certify to the agency that the electronic signatures in their system, used on or after August 20, 1997, are intended to be the legally binding equivalent of traditional handwritten signatures.	It is the responsibility of the instrument owner to send a letter to the FDA stating their intention to use electronic signatures.	
C-11.200 (a)	Electronic signatures that are not based upon biometrics shall: (1)(i)(ii) Employ at least two distinct identification components such as an identification code and password.	The signature on the KjelMaster K-375 is implemented by using a combination of username and password. The KjelMaster K-375 prompts the signature components (username and password) on the instrument login.	
	(2) Be used only by their genuine owners; and our customers need to set up appropriate procedures and policies.	It is the responsibility of the instrument owner to ensure that the signatures are only used by their genuine owners.	
	(3) Be administered and executed to ensure that attempted use of an individual's electronic signature by anyone other than its genuine owner requires collaboration of two or more individuals.	An attempt to falsify electronic signatures requires the collaboration of at least two individuals.	
(b)	Electronic signatures based upon biometrics shall be designed to ensure that they cannot be used by anyone other than their genuine owners.	The K-375 instrumentation does not offer biometric signatures. The username with password credentials are the only way to gain access to the system.	
C-11.300 (a)	Persons who use electronic signatures based upon the use of identification codes in combination with passwords shall employ controls to ensure their security and integrity. Such controls shall include: Maintaining the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification code and password.	The KjelMaster K-375 assigns a username and password uniquely to each user. Existing usernames cannot be deleted and reassigned to other users (newly created users require a new username).	

Reference section	21 CFR Part 11 Regulation Text (short description)	KjelMaster K-375 with Pharma Package	Conformity
(b)	Ensuring that identification code and password issuances are periodically checked, recalled, or revised (e.g., to cover such events as password aging).	The KjelMaster K-375 enforces a password change after 90 days. Upon expiration of the password, the user is locked out and only authorized personnel (Administrator) can unlock this user again.	
(c)	Following loss management procedures to electronically reject lost, stolen, missing, or otherwise potentially compromised tokens, cards, and other devices that bear or generate identification code or password information, and to issue temporary or permanent replacements using suitable, rigorous controls.	The KjelMaster K-375 does not use tokens, cards or other devices as authorization hardware. The username with password credentials is the only way to gain access to the system. Authorized personnel (Administrator) can, however, reset and assign new passwords to users who have forgotten their password.	
(d)	Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and to detect and report in an immediate and urgent manner any attempts at their unauthorized use to the system security unit, and, as appropriate, to organizational management.	User Lockout after incorrect login (3x), authorized personnel (Administrator) can unlock users. Authorized personnel (Administrator) can lock users (deny instrument access). Locked users are obtained (stored) and can be unlocked again by authorized personnel (Administrator).	
(e)	Initial and periodic testing of devices, such as tokens or cards, that bear or generate identification code or password information to ensure that they function properly and have not been altered in an unauthorized manner.	The KjelMaster K-375 does not use tokens, cards or other devices as authorization hardware. The username with password credentials are the only way to gain access to the system.	

4 General functionality of Pharma Package

In addition to the previously described functionalities, the KjelMaster K-375 Pharma Package takes care of some general principles that ensure compliance with the regulation. An important general function is that no user can recalculate or change any measurement results in hindsight. This ensures that the measurement data cannot be falsified. Therefore, the KjelMaster K-375 does not need to support a versioning function. Furthermore, all manual instrument control functions are disabled during measurement processes, this ensures that a method is done according to the programming. The predefined user rights are linked to the respective user levels and are not individually definable, Chapter 5 "User Management", page 13 describes the user-rights in detail.

5 User Management

The KjelMaster K-375 Pharma Package supports three user levels with predefined user rights. In general, the rights can be described as follows:

- Operator:
  This user level can conduct all measurements functions for generating new measurement results.
- Lab-Manager:
  This user level can additionally generate and modify instrument methods. Furthermore, they can approve measurement results over the print and export function. Nevertheless, access is restricted to functions such as user management, database management and time management. This user level cannot delete any measurement data on the instrument.
- Admin:
  This user level has access to all functions except the deletion of users. An intelligent export logic takes care of retaining all system event logs along with the underlying data. Therefore, all delete, export and other important actions are recorded in the system event log (audit trail) that remains completely trackable.

System Preparation

Menu	Function	Admin	Lab-Manager	Operator
Preheating	Modify	X	X	-
	Start	X	X	X
Priming	Modify	X	X	-
	Start	X	X	X
Cleaning	Modify	X	X	-
	Start	X	X	X
Aspiration	Modify, Start	X	X	X
Calibration pH electrode	Modify, Start	X	X	X
Calibration pH electrode.History	Print	X	X	X
	Delete	X	X	-
Calibration pH electrode.Chart	Print	X	X	X
Setpoint colorimetric sensor	Modify	X	X	-
	Start	X	X	X
Buret functions	Modify	X	X	-
	Start	X	X	X
Pump calibration	Modify, Start	X	X	-
Sampler functions	Modify, Start	X	X	-
Measuring pH or mV	Modify	X	X	-
	Start	X	X	X

Single Sample

Menu	Function	Admin	Lab-Manager	Operator
	Modify, Start	X	X	X

Sample List

Menu	Function	Admin	Lab-Manager	Operator
	Modify, Start, Delete, Rename, Copy, New, Import	X	X	X
	Lock, Unlock	X	X	-

Sequence

Menu	Function	Admin	Lab-Manager	Operator
	Modify, Start, Delete, Rename, Copy, New, Import	X	X	X
	Lock, Unlock	X	X	-

Result Groups

Menu	Function	Admin	Lab-Manager	Operator
	Delete.group	X *	-	-
	Rename, New	X *	X *	X *
	Print, Export	X *	X *	-
	Filter	X	X	X

Results in Groups

Menu	Function	Admin	Lab-Manager	Operator
	Delete.singlesample	-	-	-
	Print, Export	X *	X *	-
	Filter	X	X	X

Last Result

Menu	Function	Admin	Lab-Manager	Operator
	Print, Export	X *	X *	X

Blanc Correction

Menu	Function	Admin	Lab-Manager	Operator
	Settings	X	X	-
	Manual, Mean, Auto	-	-	-

Methods

Menu	Function	Admin	Lab-Manager	Operator
	Delete	X *	-	-
	Rename, Copy, New	X *	X *	-
	Export, Print	X	X	X
	Import	X	X	-

Volumetric Solutions

Menu	Function	Admin	Lab-Manager	Operator
	Delete, Rename, New, Titer.adjustment	X	X	-

Reference Substances

Menu	Function	Admin	Lab-Manager	Operator
	Delete, Rename, New	X	X	-
	Reference Substances. Adjustments	X	X	-

Settings

Menu	Function	Admin	Lab-Manager	Operator
Settings.UserAdministartion	Delete, Rename	-	-	-
	New Default Password: 12345Aa:	X *	-	-
	Set new password	X *	X *	X *
	Assign passwords, Assign user levels, Lock users, Unlock users	X *	-	-
Settings.Regional settings	Modify	X	X	X
Settings.Date and time	Modify	X *	-	-
Settings.Display and sound	Modify	X	X	X
Settings.Result units	Modify	X	X	-
Settings.Dosage volume in status view	Modify	X	X	-
Settings.Peripherals	Modify	X	X	-
Settings.Network	Modify	X	X	-
Settings.Import and export**	Modify	X	X	-
Settings.Device information	Status view	X	X	X
Settings.Service information	Modify	X	X	-
Utilities				
Utilities.Database	Modify	X	-	-
	Backup, Restore	X *	-	-
Utilities.LabTimer	Delete, Start, Stop, New	X	X	X
Utilities.Demo mode	Modify	X	X	-
Diagnostics				
Diagnostics.Service Mode	Modify	X	-	-
Diagnostics.System Events	Delete	X *	-	-
	Export	X *	X *	-
	Group, Filter	X	X	X

Global System Buttons

Menu	Function	Admin	Lab-Manager	Operator
Home		X	X	X
Status View	Manual dosing	X	X	X
	Manual dosing (during a running process)	-	-	-
	Result, Chart, Info	X	X	X
Ready, Start, Stop		X	X	X

* These interactions are logged in the system-events-log (see action logs in system-events-log table, Chapter 7 "System events log (Audit-trail)", page 17

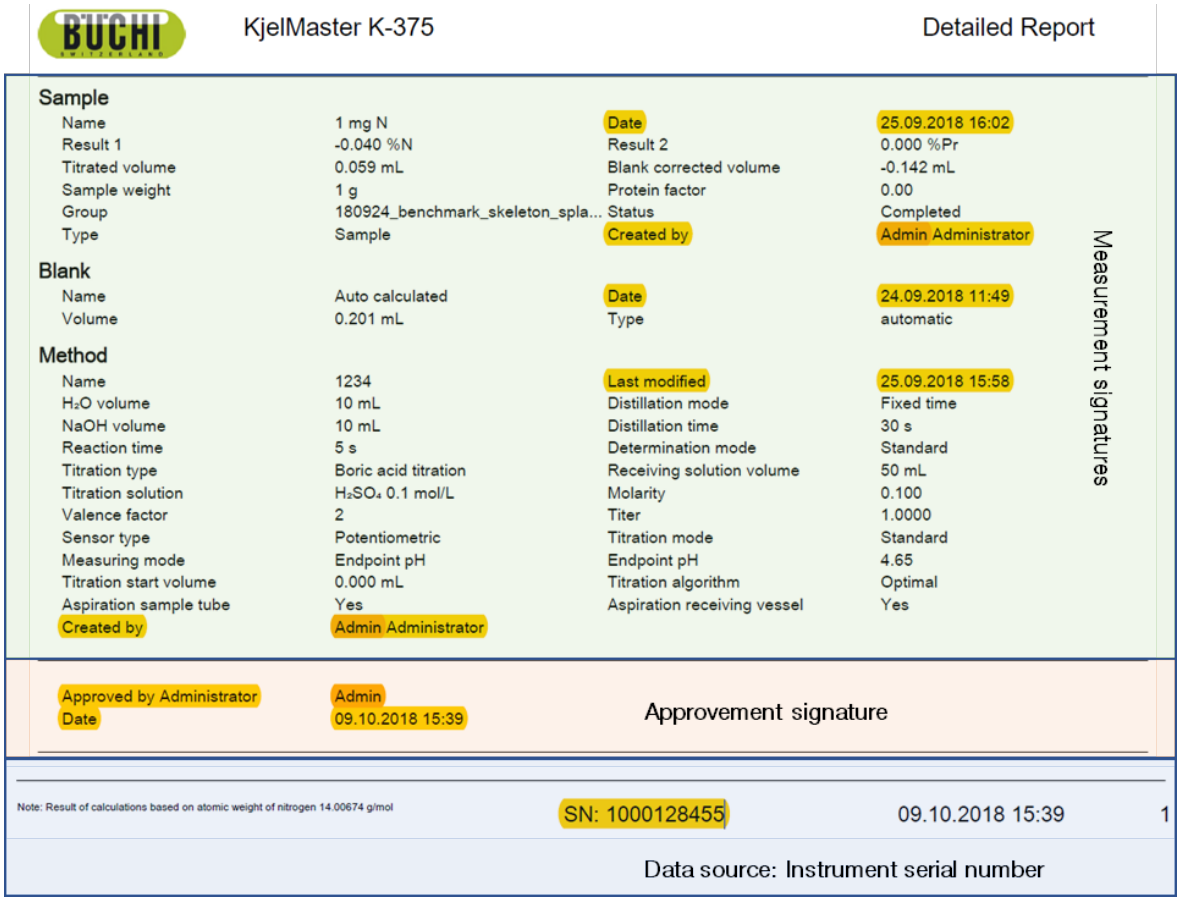
** The data export and network capabilities of the KjelMaster K-375 are described in detail in the documents: “KjelMaster K-375 Manual – Data export” (PN: 11593558) and “KjelMaster K-375 Manual – Network connection” (PN: 11593539)

6 Electronic Signatures

Measurement information; like sample, blank or method data are automatically and unambiguously signed with user name, user level and date/time of execution of the logged in user. The measurement data along with the electronic signature can be displayed at any time on the instrument itself, on pdf reports and on exported xml files.

The KjelMaster K-375 Pharma Package enables users with Administrator and Lab-Manager rights to approve measurement results through the export or print function. This functionality implements the four-eye principle to the instrumentation, because the approver is authorized to double-check the data entries, results and pH calibrations done from another user before he does an approval. Additionally, the instrument serial number is linked to the generated data too, through that, the data source is clearly defined.

The report below shows an example pdf report. All electronic signatures (username, user-level, date/time of execution, measurement approval) and the data source (instrument serial number) are highlighted in the report.



KjelMaster K-375 Detailed Report

Sample

Name	1 mg N	Date	25.09.2018 16:02
Result 1	-0.040 %N	Result 2	0.000 %Pr
Titrated volume	0.059 mL	Blank corrected volume	-0.142 mL
Sample weight	1 g	Protein factor	0.00
Group	180924_benchmark_skeleton_spla...	Status	Completed
Type	Sample	Created by	Admin Administrator

Blank

Name	Auto calculated	Date	24.09.2018 11:49
Volume	0.201 mL	Type	automatic

Method

Name	1234	Last modified	25.09.2018 15:58
H_2O volume	10 mL	Distillation mode	Fixed time
NaOH volume	10 mL	Distillation time	30 s
Reaction time	5 s	Determination mode	Standard
Titration type	Boric acid titration	Receiving solution volume	50 mL
Titration solution	H_2SO_4 0.1 mol/L	Molarity	0.100
Valence factor	2	Titer	1.0000
Sensor type	Potentiometric	Titration mode	Standard
Measuring mode	Endpoint pH	Endpoint pH	4.65
Titration start volume	0.000 mL	Titration algorithm	Optimal
Aspiration sample tube	Yes	Aspiration receiving vessel	Yes
Created by	Admin Administrator		

Measurement signatures

Approved by Administrator: Admin
Date: 09.10.2018 15:39

Approvement signature

Note: Result of calculations based on atomic weight of nitrogen 14.00674 g/mol

SN: 1000128455 09.10.2018 15:39 1

Data source: Instrument serial number

7 System events log (Audit-trail)

The system events log tracks all quality relevant data automatically and respective to the signed-in user in a human readable, exportable format. The tracking runs permanently and all entries are protected from changes by any user. An intelligent export logic takes care of retaining all event logs with the underlying data. The system events log is divided into two sections:

Actions logs: Important user interactions on K-375

Action logs	Description	Log text / message
50’001	Device powered on	system started
50’002	Device powered off	system terminated
50’003	User login	user <name>
50’004	User logout	user <name>
50’007	Automatic export error	<sample name> + <error message>
50‘008	Sequence information	<sequence name> + <error message>
50’104	Too many system events stored. Please export and delete	information window
50’105	Too many system events stored. START disabled	information window
50’110	Logon failed	user <name>. access denied.
50’111	Delete method	method <name> deleted
50’112	Result group	delete n results of group <name> rename result group name <name> to <new name> new result group <name> added print n results of group <name> export n results of group <name>
50’114	User administration	add user <username> delete user <username> rename user <username> to <newUsername> user <username> modified password of user <username>
50’115	System events	export system events, clear system events
50’116	Database	backup and restore database
50’117	Date Time	time <actual time> has changed to <new time> date <actual date> has changed to <new date> time zone <actual time zone> has changed to <new time zone>

Process logs: Instrument status information and encountered error

Process logs	Description	Solution
10’001	Process aborted by user.	▶ Information
10’002	Distillation starting point not found.	▶ Information
10’003	Last shutdown failed.	▶ Make sure the device is switched off by pushing the power switch. ▶ Information
10‘004	Method without aspiration.	▶ Aspiration required with sampler. ▶ Reprogram the method.
10‘005	Demo mode is activated.	▶ Information
10’011	Real time clock battery is low. Date and time have been reset.	▶ Set correct date and time in settings. ▶ Change the battery. ▶ Contact BUCHI Costumer Service.
10’101	Door is open.	▶ Close the door.
10’102	No sample tube present.	▶ Insert a sample tube.
10’103	Tube shield is open.	▶ Close the tube shield.
10’104	Preheating is recommended.	▶ Preheating the instrument.
10’110	The burette is disconnected	▶ Connect a burette.
10’121	H2O tank is empty.	▶ Refill the H_2O tank.
10’122	NaOH tank is empty.	▶ Refill the NaOH tank.
10’123	H3BO3 tank is empty.	▶ Refill the H3BO3 tank.
10’124	Waste receiver tank is full.	▶ Empty the waste receiver tank.
10’125	Waste sample tube tank is full.	▶ Empty waste sample tube tank.
10‘126	Acid tank is empty.	▶ Refill the acid tank.
10’200	Sensor 'pump current' is out of order.	▶ Contact BUCHI Costumer Service.
10’204	Sensor 'cooling water flow' is out of order.	▶ Contact BUCHI Costumer Service.
10’208	Sensor 'steam pressure' is out of order.	▶ Contact BUCHI Costumer Service.
10’217	AD converter is out of order.	▶ Contact BUCHI Costumer Service.
10’300	No cooling water flow detected.	▶ Open water tap.
10‘301	Aspiration error: No vacuum detected.	▶ Contact BUCHI Costumer Service.
10‘302	Cooling water flow is too low.	▶ Examine parameters in Settings.Peripherals.Cooling water settings
10‘303	Low pressure during distilling	▶ Examine sealings.
10‘311	Pump H2O has no current.	▶ Contact BUCHI Costumer Service.
10’312	Pump NaOH has no current	▶ Contact BUCHI Costumer Service.
10’314	Pump H3BO3 has no current	▶ Contact BUCHI Costumer Service.
12’001	Valve steam (Y1) is out of order.	▶ Contact BUCHI Costumer Service.
12’002	Valve cooling water in (Y5) is out of order.	▶ Contact BUCHI Costumer Service.
12’003	Valve sampler steam (Y6) is out of order.	▶ Contact BUCHI Costumer Service.
12’004	Valve sampler transfer (Y7) is out of order.	▶ Contact BUCHI Costumer Service.
12’005	Valve 5 (not used) is out of order.	▶ Contact BUCHI Costumer Service.
12’006	Valve waste sample tube (Y2) is out of order.	▶ Contact BUCHI Costumer Service.
12’007	Valve aspiration in (Y3) is out of order.	▶ Contact BUCHI Costumer Service.
12’008	Valve receiver (Y4) out of order	▶ Contact BUCHI Costumer Service.

Process logs	Description	Solution
12’009	Valve H2O injection (Y8) out of order	▶ Contact BUCHI Costumer Service.
12’010	Valve H2O sample tube (Y9) out of order	▶ Contact BUCHI Costumer Service.
12’011	Valve waste receiver (Y10) is out of order.	▶ Contact BUCHI Costumer Service.
13’001	27V power supply overcurrent	▶ Contact BUCHI Costumer Service.
13’002	Ventilator power overcurrent	▶ Contact BUCHI Costumer Service.
13’003	Ventilator electronics is blocked.	Examine the ventilator. ▶ Contact BUCHI Costumer Service.
13’004	Ventilator interior is blocked.	▶ Examine the ventilator. ▶ Contact BUCHI Costumer Service.
14’001	Titrator is not ready.	▶ Examine power cable to titrator. ▶ Contact BUCHI Costumer Service.
14’002	Titrator information (version)	
14‘003	Titrator not started.	▶ Examine titrator functionality. ▶ Contact BUCHI Costumer Service.
14‘004	Titrator not started, pH value is too low.	▶ Change parameter. Check sensor and calibration.
14‘005	Titrator not started, pH value too high	▶ Change parameter. Check sensor and calibration.
14’006	Wrong titration direction	▶ pH sensor not in measurement solution? wrong titrant or calibration?
14’007	End of titration, pH value too low	▶ Change titration parameter. Check sensor and calibration.
14’008	End of titration, pH value is too high.	▶ Change parameter.
14’010	Titrator module could not create service 11.	▶ Reboot the instrument.
14’011	Titrator module could not create service 21.	▶ Reboot the instrument.
14’012	Titrator module could not create service 41.	▶ Reboot the instrument.
14’013	Titrator module could not create service 3.	▶ Reboot the instrument.
14’100	Titrator timeout endpoint not reached.	▶ Change parameter.
14’101	Titrator measured value is out of range.	▶ Calibrate the ph-value.
14’501	Dosing unit not ready.	▶ Examine dosing unit.
14’502	Dosing unit locked.	▶ Examine dosing unit.
14’503	Dosing unit not ready, no exchange unit.	▶ Examine dosing unit.
14’504	Dosing unit not ready.	▶ Examine dosing unit.
14’505	Dosing unit overload.	▶ Examine dosing unit.
14’506	Dosing unit not ready, cock blocked.	▶ Examine dosing unit.
14’602	Titrator stopped, maximal volume reached.	▶ Examine parameters.
14’603	Titrator stopped, endpoint reached.	▶ Examine parameters.
14’604	Titrator stopped, stopPot reached.	▶ Examine parameters.
14’605	Titrator stopped, stop time reached.	▶ Examine parameters.
15’001	No sampler connected.	▶ Switch the sampler on.
15’002	Sampler: Target not achieved.	▶ Examine sampler. ▶ Contact BUCHI Costumer Service.
15’003	Sampler: Connection lost.	▶ Examine RS-232 cable.
15’101	Sampler: Shield open.	▶ Close the shield.

Process logs	Description	Solution
15’102	Sampler: Crash detected	▶ Reboot the sampler. ▶ Contact BUCHI Costumer Service.
15’103	Sampler: Tube not found	▶ Insert sample tube.
15’104	Sampler: Tube not released	▶ Reboot the sampler. ▶ Contact BUCHI Costumer Service.
15’107	Sampler: Shield not locked	▶ Close the shield.
15’108	Sampler: Error reference position	▶ Reboot the sampler. ▶ Contact BUCHI Costumer Service.
15’109	Sampler zero adjustment not possible because x or y deviation is larger than 3 mm or sampler was not in reference position before adjustment start.	▶ Reboot the sampler. ▶ Contact BUCHI Costumer Service.
15’110	Sampler: Position error X-axis	▶ Reboot the sampler. ▶ Contact BUCHI Costumer Service.
15’111	Sampler: Position error Y-axis	▶ Reboot the sampler. ▶ Contact BUCHI Costumer Service.
15’112	Sampler: Position error Z-axis down	▶ Reboot the sampler. ▶ Contact BUCHI Costumer Service.
15’113	Sampler: Position error Z-axis up	▶ Reboot the sampler. ▶ Contact BUCHI Costumer Service.
15’114	Sampler: Error during EEPROM writing. Adjustment value not saved.	▶ Reboot the sampler. ▶ Contact BUCHI Costumer Service.
17’001	Steam generator overtemperature.	▶ Open water tap. ▶ Contact BUCHI Costumer Service.
17’002	Water level not reached.	▶ Open water tap. ▶ Contact BUCHI Costumer Service.
18’001	Stirrer out of order.	▶ Examine stirrer cable.
50’005	Verify data consistency time.	▶ Information
50‘006	Device power failure during determination.	▶ Information

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