



CoaguChek[®] XS Pro System

*Supplement v2.0 to the
Operator's Manual v5.0*

CoaguChek[®]



Document version	Date	Content
1.0	2019-11	New document, created as an amendment to Operator's Manual Version 5.0
2.0	2021-02	Update for SW 03.05.01: added information on TLS encryption and display functionality.

Purpose of document

This document provides a description of changes to the Operator's Manual version 5.0 for SW 03.05.xx. This addendum is valid for and intended to be used in conjunction with the CoaguChek XS Pro Operator's Manual version 5.0. It is not a replacement for the complete CoaguChek XS Pro Operator's Manual version 5.0. Changes or additions to the information in the CoaguChek XS Pro Operator's Manual version 5.0 are shown in color.



Be sure to read the complete CoaguChek XS Pro Operator's Manual version 5.0.

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Caution: Federal law restricts this device to sale by or on the order of a physician.

This manual was created by the Roche Diagnostics Engineering Operations department. Direct questions or concerns regarding the contents of this document to:

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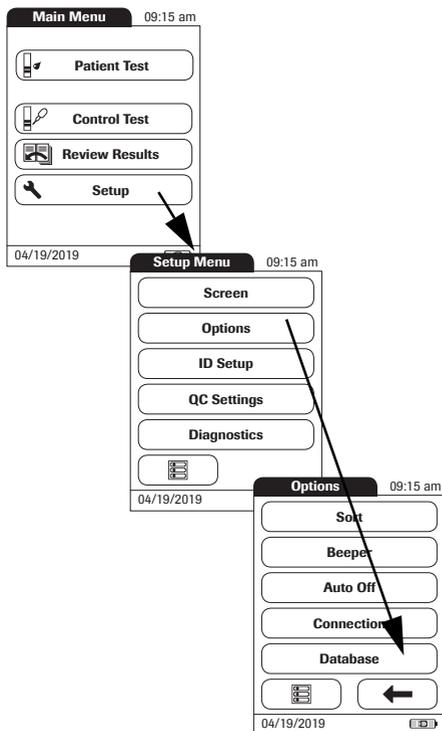
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1 What is new in SW 03.05?

Options setup

Database

In the *Database* menu¹ you can set up your CoaguChek XS Pro meter to automatically delete test results after a certain time period, and/or delete stored information (test results and code chip data) manually.

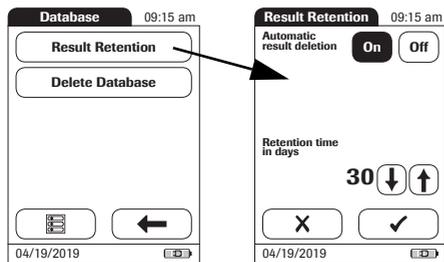


- 1 From the *Main Menu*, touch **Setup** to open the meter settings.
- 2 From the *Setup Menu*, touch **Options**.
- 3 From the *Options* menu, touch **Database**.

1. If an *Admin.* password has been set on the meter, the *Connection* and *Database* setup areas are only available to the system administrator.

Result Retention

In the *Result Retention* menu you can enable or disable automatic deletion of test results after a selectable time period.



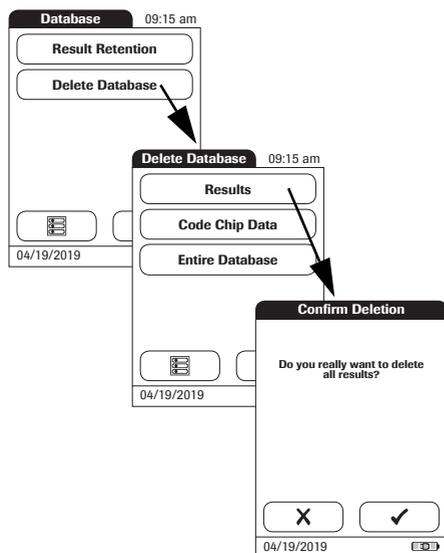
- 1 From the *Database* menu, touch **Result Retention**.

You may select from the following deletion options:

- **Off** (test results will never be deleted automatically)
 - **On** (test results will be deleted automatically after the time period set below)
- 2 Touch  or  to select the time period in days, after which data will be deleted automatically.
 - 3 Touch  to save this setting, or touch  to exit this menu without saving any changes. The display automatically returns to the previous screen.

Delete Database

In the Delete Database menu you can manually delete all test results, code chip data, or the entire database.

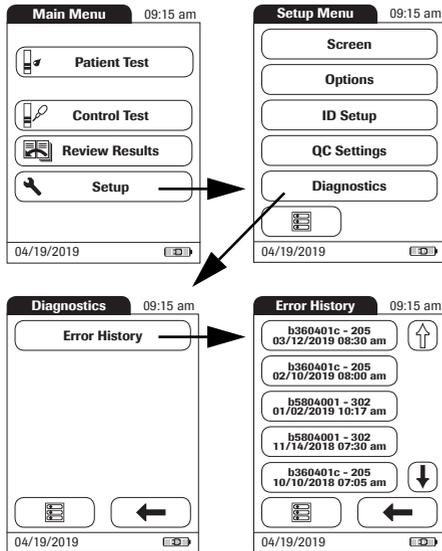


- 1 From the *Database* menu, select the type of data you want to delete:
 - **Results** (all stored test results)
 - **Code Chip Data** (all stored code chip data)
 - **Entire Database** (all test results, comments, code chip data, operator and patient IDs)
- 2 Touch ✓ to confirm the deletion, or touch ✕ to exit this function without deleting data.

Diagnostics

Error History

Use the *Diagnostics* menu¹ to access the *Error History* of the meter. All errors occurring during internal self tests or regular operation are logged in this list.



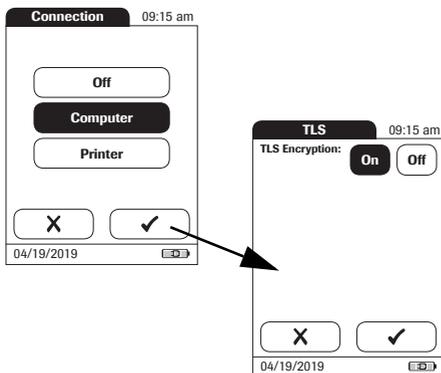
- 1 From the *Main Menu*, touch **Setup** to open the meter settings.
- 2 From the *Setup Menu*, touch **Diagnostics**.
- 3 From the *Diagnostics* menu, touch **Error History**.
- 4 Touch  and  to scroll to the entry of choice on the screen.

1. If an *Admin.* password has been set on the meter, the *Diagnostics* setup area is only available to the system administrator.

2 What is new in SW 03.05.01?

The following information has been **changed** on page 57:

Computer



- 4 Touch **Computer**. Your selection is now highlighted.
- 5 Touch **✓** to select the desired option for TLS Encryption next, or touch **X** to exit this menu without saving any changes.
- 6 **TLS Encryption**: Touch **On** if you want to turn on encryption for all computer communication. Otherwise touch **Off**.
- 7 Touch **✓** to save this setting, or touch **X** to exit this menu without saving any changes. The display automatically returns to the *Options* screen.

3 Amendments to Operator's Manual version 5.0

Revised sections

Important safety instructions and additional information

The following information has been **added** on page 16:



Avoidance of electrical shock, fire, and explosions

- Only use Roche original accessories (cables, power supply units, battery packs, and spare parts). Third-party cables, power supply units, and battery packs can cause the battery pack to explode or the meter to become damaged.
 - Do not use loose power sockets or damaged power supply units, cables, plugs, or battery packs **and batteries**.
 - Do not short circuit the power supply unit, the handheld base unit contacts, or the battery pack.
 - Do not drop the CoaguChek XS Pro meter, the power supply unit, or the battery pack and protect these against shaking and vibrations.
-

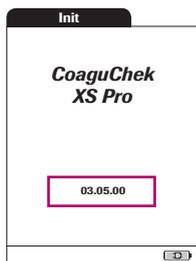
Local Area Network: protection from unauthorized access

The following information has been revised and/or added on page 20:

- If this meter is connected to a local area network, this network must be protected against unauthorized access. In particular, it must not be linked directly to any other network or the Internet. Customers are responsible for the security of their local area network, especially in protecting it against malicious software and attacks. This protection might include measures, such as a firewall, to separate the device from uncontrolled networks as well as measures that ensure that the connected network is free of malicious code. If user data and/or passwords are altered by means of a compromised DMS the meter might become unusable.
- If you use a customized data management system solution, ensure that sensitive data transmitted via the POCT1-A interface is protected by appropriate security measures.
- Ensure that the instrument is protected against unauthorized physical access and theft.
- Do not use shared user or operator accounts on meter, DMS, and network.
- Use a strong password for user or operator accounts on the meter, DMS, and network. Observe your own facility guidelines on password management where available, or apply the rules for strong passwords, see “Characteristics of strong passwords” below.

Checking the software version

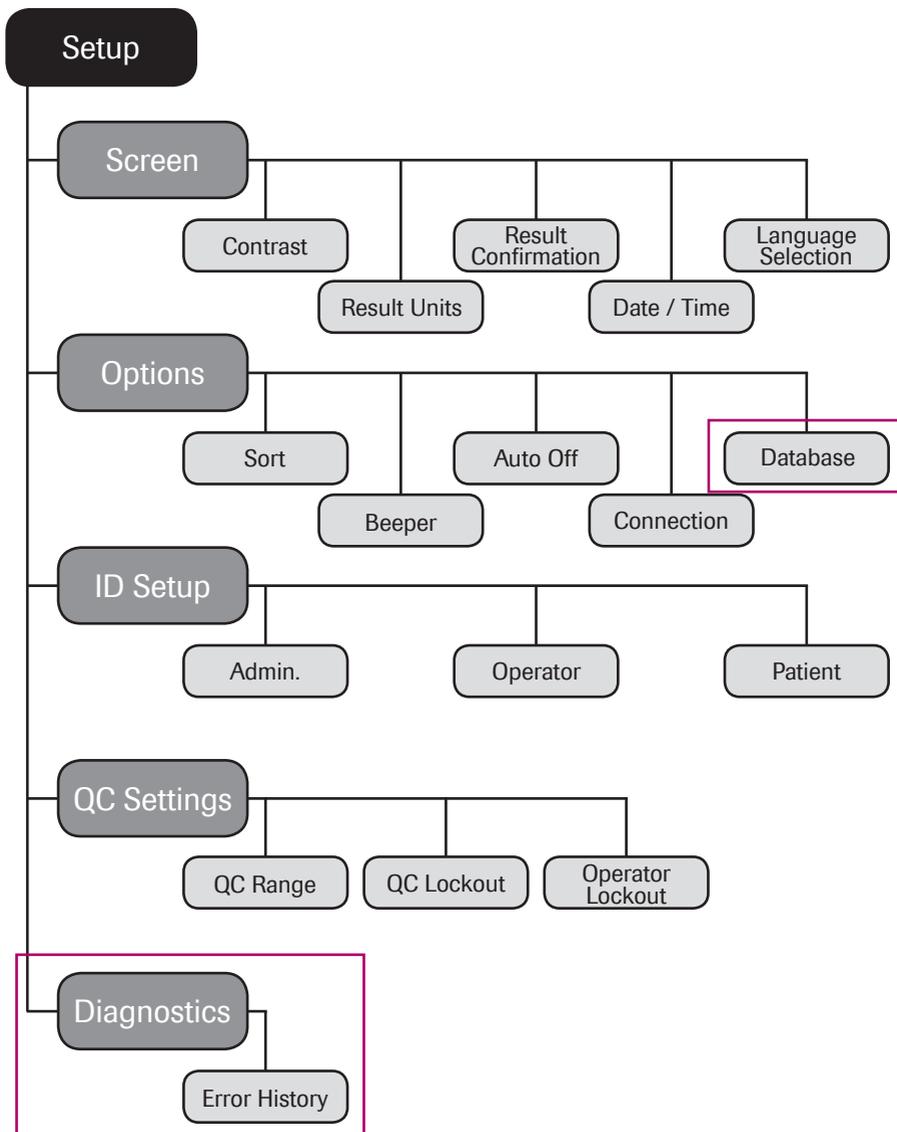
The following information has been revised on page 31:



After displaying the Roche logo, the meter briefly displays the *Init* (for “initialization”) screen. Here you can check which software version is currently running on your meter. (The Init screen shown here is for illustration purposes only. Version numbers on your meter may differ.)

Settings summary

The following illustration has been revised on page 34:



The following information has been added on page 36:

Group	Subgroup	Setting	Values *	
Options	Sort		Date/Time *	
			Patient ID	
			Patient Name	
	Beeper	Beeper		Off
				Low
				Medium *
				High
	Auto Off	[minutes]		Off
				1 ... (5*) ... 10
				15
				20
				25
				30
				40
				50
			60	
Connection				
			Computer (TLS encryption On/Off*)	
Database	Result Retention		Automatic result deletion On/Off*	
			Retention time in days: 1 ... 30* ... 1000	
	Delete Database		Results Code Chip Data Entire Database	

* Default settings are labelled with an asterisk (*).

The following information has been added on page 37:

Group	Subgroup	Setting	Values *
ID Setup	Admin. (Administrator)		Blank (Off) *
	Operator (Operator List is optional)		Active
			Inactive *
	Patient		No *
			Optional
		Required	
QC Settings	QC Range	Default Range*	
		Custom Range	Display Target Value On/Off *
			Deviation from Target Value Percentage (%)
	Operator Lockout (only if the <i>Operator</i> option is set to <i>Active</i> and an operator list is available)		Off *
			Weekly
			Monthly
			Every 3 months
			Every 6 months
	QC Lockout	New code	Yes
			No *
		General	No *
			Daily
Weekly			
Monthly			
Diagnostics	Error History		

* Default settings are labelled with an asterisk (*).

The following information has been added on page 139:

Errors and unusual behavior without error messages

Some conditions may arise that have no associated error or status message.

If you notice any issues with the display functionality (e.g. unexpected lines/marks on the meter display), stop using the system and contact Roche Customer Support Center at 1-800-428-4674.

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