CoaguChek® XS Plus System
Supplement v2.0 to the
Operator's Manual v9.0

CoaguChek®

Document version	Date	Content
1.0	2019-11	New document, created as an amendment to Operator's Manual Version 9.0
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 9.0 for SW 03.05.xx. This addendum is valid for and intended to be used in conjunction with the CoaguChek XS Plus Operator's Manual version 9.0. It is not a replacement for the complete CoaguChek XS Plus Operator's Manual version 9.0. Changes or additions to the information in the CoaguChek XS Plus Operator's Manual version 9.0 are shown in color.

⚠️

Be sure to read the complete CoaguChek XS Plus Operator's Manual version 9.0.

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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1   What is new in SW 03.05?

Options setup

Database

In the *Database* menu[1] you can set up your CoaguChek XS Plus meter to automatically delete test results after a certain time period, and/or delete stored information (test results and code chip data) manually.
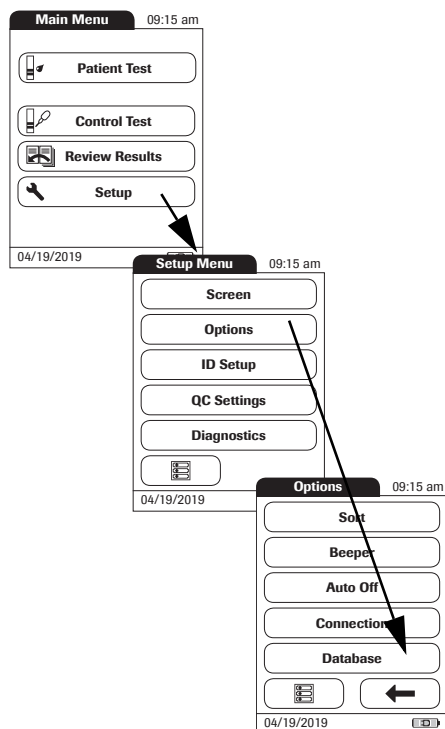
1   From the *Main Menu*, touch **Setup** to open the meter settings.

2   From the *Setup Menu*, touch **Options**.

3   From the *Options* menu, touch **Database**.

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

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Result Retention

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

Database	09:15 am
Result Retention	
Delete Database	
04/19/2019	

Result Retention	09:15 am
Automatic result deletion	On Off
Retention time in days	30 ↓ ↑
✕	✓
04/19/2019	

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

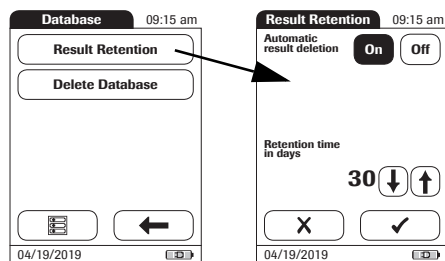You may select from the following deletion options:

- ■ **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.
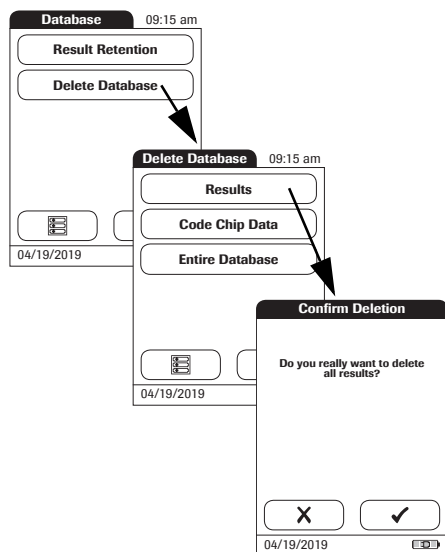
1 From the *Database* menu, select the type of data you want to delete:

■ **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

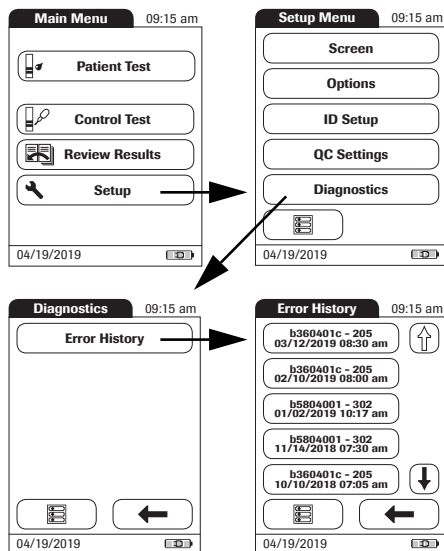Use the *Diagnostics* menu[1] to access the *Error History* of the meter. All errors occurring during internal self tests or regular operation are logged in this list.

Main Menu 09:15 am Patient Test Control Test Review Results Setup 04/19/2019	**Setup Menu** 09:15 am Screen Options ID Setup QC Settings Diagnostics 04/19/2019

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.

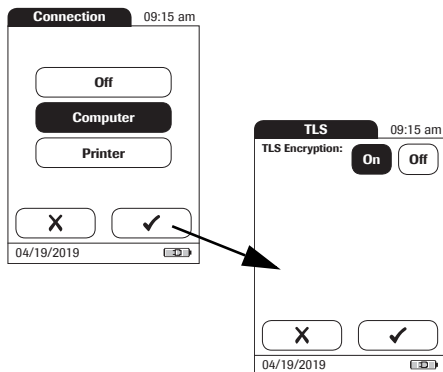|	
Diagnostics 09:15 am Error History 04/19/2019	**Error History** 09:15 am b360401c – 205 03/12/2019 08:30 am b360401c – 205 02/10/2019 08:00 am b5804001 – 302 01/02/2019 10:17 am b5804001 – 302 11/14/2018 07:30 am b360401c – 205 10/10/2018 07:05 am 04/19/2019

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 55:

Computer

Connection	09:15 am
Off	
Computer	
Printer	

04/19/2019

TLS	09:15 am
TLS Encryption:	On Off

04/19/2019

4   Touch **Computer**. Your selection is now highlighted.

5   Touch ✔ to select the desired option for TLS Encryption next, or touch ✖ 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 ✖ to exit this menu without saving any changes. The display automatically returns to the _Options_ screen.

3   Amendments to Operator's Manual version 9.0

Revised sections

Important safety instructions and additional information

The following information has been added on page 16:

⚠️
WARNING

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 Plus meter, the power supply unit, or the battery pack and protect these against shaking and vibrations.

The following information has been added on page 20:

Local Area Network: protection from unauthorized access

■ 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.

Wired network connection

If the Handheld Base Unit from Roche is used to connect this meter to a local area network, the Handheld Base Unit must be protected against unauthorized access by means of a **strong password management**. Observe your own facility guidelines on password management where available, or apply the following rules:

Characteristics of strong passwords

■   Passwords must not contain the user's account name or parts of the user's full name that exceed two consecutive characters.

■   Passwords must be at least eight characters in length.

■   Passwords must contain characters from at least three of the following four categories:

–   English **uppercase alphabetic** characters (A through Z)

–   English **lowercase alphabetic** characters (a through z)

–   **Numeric** characters (0 through 9)

–   **Non–alphabetic** characters (for example, !, $, #, %)

Examples of weak passwords

■   **uhxwze11** contains no upper case letter.

■   **UHXW13SF** contains no lower case letter.

■   **uxxxxx7F** contains the same character more than four times.

■   **x12useridF** contains a substring of the user ID longer than four characters.

Checking the software version

The following information has been revised on page 30:
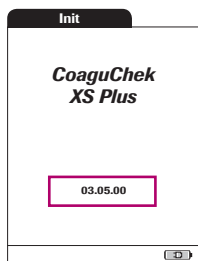
After displaying the Roche logo, the meter briefly displays the *Init* (for "initialization") screen. Here you can check which software version is currently running on your meter. (The Init screen shown here is for illustration purposes only. Version numbers on your meter may differ.)

Settings summary

The following illustration has been revised on page 32:
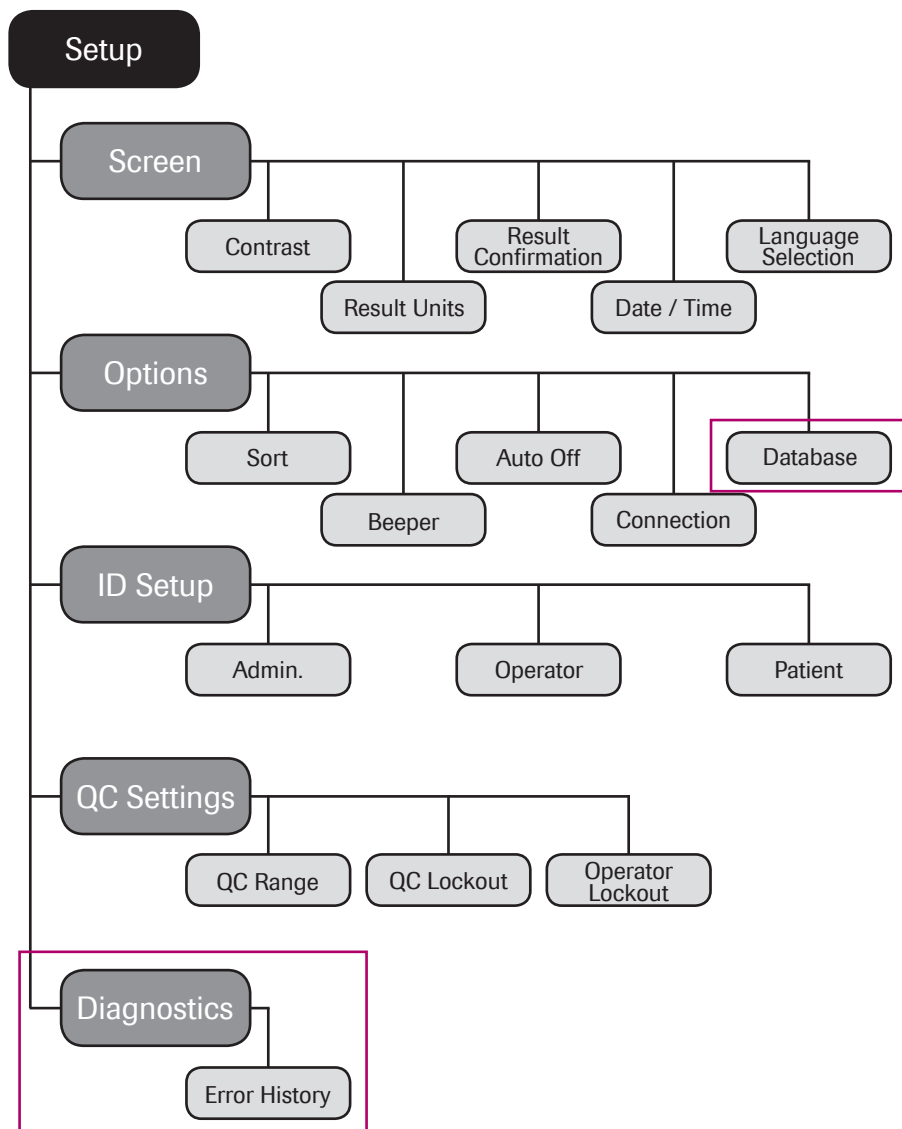
The following information has been added on page 34:

Group	Subgroup	Setting	Values *
Options	Sort		Date/Time *
			Patient ID
			Patient Name
	Beeper	Beeper	Off
			Low
			Medium *
			High
		Key Click	Off *
			On
	Auto Off	[minutes]	Off
			1 … (5*) … 10
			15
			20
			25
			30
			40
			50
			60
	Connection		Off *
			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 35:

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 *Operator* option is set to *Active* and an operator list is available)		Off *
			Weekly
			Monthly
			Every 3 months
			Every 6 months
			Yearly
	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 135:

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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