

Diagnostics Assessment Programme

Technical supplement: Summary of main changes to the CoaguChek XS system

Atrial fibrillation and heart valve disease: self- monitoring coagulation status using point-of-care coagulometers

16 May 2018

1 Background

This technical supplement is linked to the diagnostics guidance on [atrial fibrillation and heart valve disease: self-monitoring coagulation status using point-of-care coagulometers](#).

The CoaguChek XS system has been updated since publication of this guidance. This technical supplement provides information on the version of the technology included in the guidance and highlights the major features of the updated version. It does not include information on any new technologies launched since publication of the guidance. This technical supplement does not update or change the recommendations in the guidance. The guidance applies to the versions of the technology described in this technical supplement.

2 Technical information

The CoaguChek XS system (Roche Diagnostics Limited) is no longer available in the UK, but use of the device is still supported by the company and the testing strips are still available. It has been replaced with an updated version, the CoaguChek INRange, which has been available since May 2017.

This model has the same functionality, but has new features to make the device easier to use, for example, the ability to set reminders to take the test and to transfer data by Bluetooth.

The technical specifications of the CoaguChek XS system and the CoaguChek INRange system are presented in table 1.

Table 1 Technical specifications of the CoaguChek XS system and the CoaguChek INRange

Technical specification	CoaguChek XS system (model no longer available)	CoaguChek INRange
Detection system	Amperometric (electrochemical) determination of the prothrombin time after activation of coagulation with human recombinant thromboplastin	
Intended use	Professional and lay use	Patient self-testing only
Sample type	Fresh capillary whole blood or non-anticoagulated venous whole blood	Fresh capillary whole blood
Sample size	8 microlitres	8 microlitres
Compatible strips	CoaguChek XS PT Test PST CoaguChek XS PT Test	CoaguChek XS PT Test PST
Measurement time after application of blood	About 1 minute	About 1 minute
Measurement range (international normalised ratio; INR)	0.8 to 8	0.8 to 8
On-board (automatic) quality control	Yes	Yes
Display of results in specific target ranges	No	Yes
Ability to add comments to test results	No	Yes
Can set reminders to take test	No	Yes
Memory capacity	300 test results	400 test results
Time to power off with no action	3 minutes	2 minutes
Battery operation	4 × 1.5 V AAA alkaline batteries	4 × 1.5 V AAA alkaline batteries
Operating temperature	15 to 32°C	15 to 32°C
Operating relative humidity	10 to 85%	10 to 85%
Maximum altitude	4,300 m	4,300 m

Dimensions	About 138 × 78 × 28 mm	About 145 × 75 × 30 mm
Weight (not including batteries)	127 g	135 g
Storage and transport conditions	-25 to 70°C	-25 to 70°C
Trend and target range reports	Not available	Visible on device screen and on PC (connection by USB)
Data transfer (communication protocol)	Infrared (proprietary protocol)	Bluetooth classic (IEEE 11073–10418, Continua certified) USB (IEEE 11073–10418, Continua certified) Bluetooth low energy (proprietary protocol)
Data transfer direct from device to healthcare provider	No	Yes, requires healthcare system apps such as those provided by LumiraDX and InHealthcare.
CE marking or licensing information	CE IVD 98/79/EG, dated 2012 and updated in 2016	CE IVD 98/79/EG, awarded on 15 February 2017
Price (as at April 2018) Prices are excluding VAT	Device is no longer available for purchase. CoaguChek XS PT Test PST test strips (per unit): £2.91 Lancets (per unit): £0.04	Device cost: £299 CoaguChek XS PT Test PST test strips (per unit): £2.91 Lancets (per unit): £0.04

Look online or contact [Roche Diagnostics](#) for further information on the [CoaguChek INRange system](#).