

Product Update:

epoc System Manual, Updates (June 2021)

Overview

This product update announces the release of an updated **epoc® System Manual**.

This new revision incorporates several new Host and Reader features and enhancements, content clarification, website information adjustments and additional symbols.

Actions Required

Please review this update in its entirety and contact Siemens Healthineers Remote Services Center or your local Siemens technical support representative if you have any questions.

This update supersedes all prior epoc System Manual updates. Please destroy all previous versions and replace them with the new version provided.

	English
Old Manual	51012382 Rev. 02
New Manual	51012382 Rev. 03

CLSI Template Document

epoc Blood Analysis System Procedure Manual (template document prepared in accordance with the guidelines recommended by CLSI) has been updated to reflect the latest changes to Sections 9 and 12. Please use 51008148 Rev. 09. This document is available in English only.

Description of Changes

The updated epoc System Manual incorporates several new Host features and enhancements, website information adjustments and content clarifications, as outlined in the table below.

The following table provides detailed change information for the English epoc System Manual 51012382 Rev. 03, as compared to 51012382 Rev. 02, by section. Page numbers reflect numbering in the English document. The sections omitted from the table below have not been changed, other than for replacing the old document revision Rev. 02 with Rev. 03 and minor formatting.

Section	Change Description (from 51012382 Rev. 02, to 51012382 Rev. 03)	Page
Cover	<ul style="list-style-type: none">Added eIFU symbolUpdated website informationUpdated Siemens Healthcare Diagnostics copyright statement for 2021	Pg. 1 Pg. 1 Pg. 1
1	Added new subsections: 1.6 Serious Incident Reporting and 1.7 IT Security	Pg. 1-3
4	Section 4.3 Test Card Packaging, Storage, and Shelf Life <ul style="list-style-type: none">Removed the image of shipping carton as not applicable	Pg. 4-2

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5	Section 5.7 Card Insertion Slot <ul style="list-style-type: none"> Added description of barcode scanner behavior as per new Reader firmware 	Pg. 5-5
7	Section 7.7.2 General Configuration Page <ul style="list-style-type: none"> Reworded subsection "D. Enable FIPS mode?" Replaced two screenshots displaying reference to FIPS mode 	Pg. 7-6 Pgs. 7-4, 7-6
9	Section 9.2.1.B Verification of Card Shipment <ul style="list-style-type: none"> Removed "in duplicate" Section 9.2.2.B Verification of Thermal Control System (Thermal QA) <ul style="list-style-type: none"> Removed requirement for bi-annual Thermal QA verification. 	Pg. 9-1 Pg. 9-2
10	Section 10.3 Cleaning <ul style="list-style-type: none"> Added bleach as an approved cleaning method 	Pg. 10-2
12 51015398 Up-revved to Rev. 03	Section 12.1 Indications for Use – epoc Blood Analysis System <ul style="list-style-type: none"> Added Rx symbol and adjusted the wording of the "Intended Use" statement Section 12.2 Test Card Configuration and Use <ul style="list-style-type: none"> Added "SMN 10736382" for Crea test cards Section 12.4.8.D Limitations and Interferences <ul style="list-style-type: none"> Updated interference data for $p\text{CO}_2$ with insignificant endogenous interferent $p\text{O}_2$ Section 12.11.7.B Linearity data <ul style="list-style-type: none"> Updated linearity data for Glucose (minor typographical correction) 	Pg. 12-1 Pg. 12-2 Pg. 12-19 Pg. 12-54
13	Section 13.1 epoc Reader and 13.2 epoc Reader Accessories: <ul style="list-style-type: none"> Added Power Partners AC adapter (Model PEAMW20I-10) Section 13.5 epoc Host ² (Zebra) <ul style="list-style-type: none"> Added information on MC55X devices (Model MC55E0) 	Pg. 13-2 Pg. 13-6

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14	Section 14.5 Resetting the epoc Host (Zebra) <ul style="list-style-type: none">• New section Section 14.6 (formerly 14.5) epoc Host Application Messages <ul style="list-style-type: none">• Added error codes to some messages• Added new messages (for E36, E41, E46, E47, E48) epoc Host Screen Alignment is now 14.7 (formerly 14.6)	Pgs. 14-2 Various Page 14-16 Page 14-22
15	Section 15.1 Symbols <ul style="list-style-type: none">• Added Near-Patient symbol	Pg. 15-2
B 51005527	New revision (Rev. 15) is available	All pages
C 51000848	New revision (Rev. 09) is available	All pages
D 51003903	New revision (Rev. 12) is available	All pages
E 51011873 Up-revved to Rev. 06	<ul style="list-style-type: none">• Adjusted Grace Period description• Added eIFU symbol	Pg. 18 Pg. 20

Questions

If you have any questions, please contact Siemens Healthineers Remote Services Center or your local Siemens technical support representative.

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