Roche

Accu-Chek® Inform II

BLOOD GLUCOSE MONITORING SYSTEM

Supplement to the Operator's Manual v3

Changes from SW 03.04 to SW 03.05 and 03.06 and Amendments to Operator's Manual v3

ACCU-CHEK®

Revision History

Document version	Revision date	Changes
Version 1.0	2018-09	New Document, created for SW 03.05/SW03.06 and as an amendment to Operator's Manual Version 3.0 for SW 03.04.

Purpose of document

This document provides additional information to the Operator's Manual.

This supplement is valid for and intended to be used in conjunction with the Accu-Chek® Inform II Operator's Manual version 3.0. It is not a replacement for the complete Accu-Chek Inform II Operator's Manual version 3.0.

Be sure to read the complete Accu-Chek Inform II Operator's Manual version 3.0.

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1 What is new in SW 03.05

1.1 Change to workflow when inserting test strips

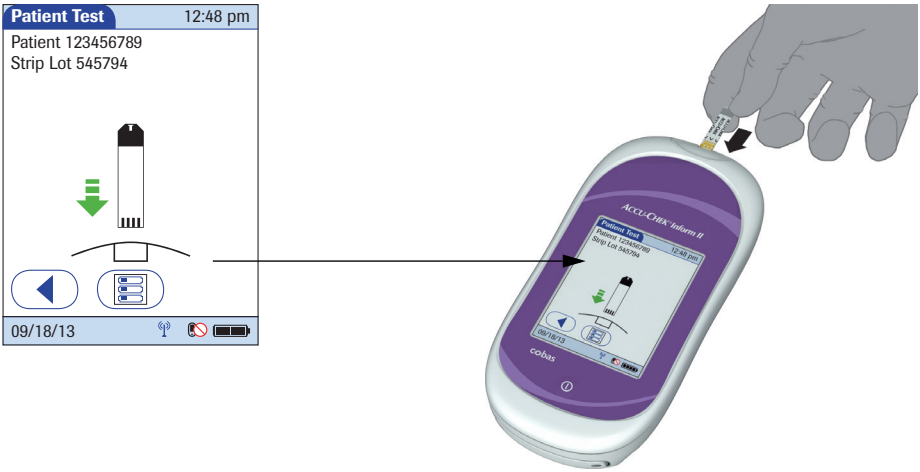
Description

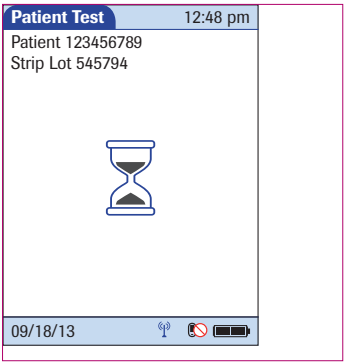
In SW 03.05 the hourglass icon appears after the test strip has been inserted to indicate that the meter is checking the test strip.

This new workflow applies whenever you perform a test, whether patient glucose test, control test, proficiency, or linearity.

Inserting test strips

After confirming the test strip lot, a flashing green arrow appears on screen and prompts you to insert the test strip.





1 Remove the test strip from the test strip vial and immediately close the cap on the vial.

2 Hold the test strip so the lettering “ACCU-CHEK” is facing upward.

3 Slide the test strip into the test strip port as far as it goes in the direction indicated by the arrows on the test strip.

The meter beeps. The hourglass icon appears and indicates that the meter is checking the test strip. Do not apply blood while it is displayed.

2 What is new in SW 03.06

This update applies for the following meters with a serial number below UU14000000:

- Accu-Chek Inform II Meter REF 05060311001 (meter only)
- Accu-Chek Inform II Meter REF 05060303001 (meter, equipped with RF card)

2.1 TLS encrypted WLAN communication

Communication via WLAN can be encrypted in the same way as wired communication between base unit and DMS. This option can only be configured via a DMS.

Manual v3.0, page 150

Old:

Subject/Attribute	Range	Default	Device	DMS
Electronic communication				
Download warning	0 – 999 h	0: disabled	N	Y
Download Lockout	0 – 999 h	0: disabled	N	Y
Maximum number of list items transferred in one POCT1-A message	1 – 500	75	N	Y
Application timeout (within this time the application expects a response by the DMS to any POCT1-A command)	5 – 6,000 s	60	N	Y

New:

Subject/Attribute	Range	Default	Device	DMS
Electronic communication				
Download warning	0 – 999 h	0: disabled	N	Y
Download Lockout	0 – 999 h	0: disabled	N	Y
Maximum number of list items transferred in one POCT1-A message	1 – 500	75	N	Y
Application timeout (within this time the application expects a response by the DMS to any POCT1-A command)	5 – 6,000 s	60	N	Y
TLS Encryption of WLAN communication	0: disabled 1: enabled	0	N	Y

3 Amendments to Operator's Manual version 3.0

3.1 Corrections

The following information was incorrect in the Operator's Manual version 3.0 (document **0 5234646002** 2013-03 USA).

Manual v3.0, page 142

Old:

Specification		Code key reader	
Storage temperature		2 to 25 °C 36 to 77 °F	
Relative humidity (storage)		< 93%	

New:

Specification		Code key reader	
Operating temperature		3 to 50 °C 37 to 122 °F	
Storage temperature (short-term)		3 to 50 °C 37 to 122 °F	
Relative humidity (short-term storage)		< 93%	

Manual v3.0, page 151 **Old:**

WLAN settings (security)				
Security Type *	0: open (no security/ encryption) 1: WEP 2: WPA_PSK (WPA with pre-shared key) 3: WEP2 4: EAP**	0	N	Y

New:

WLAN settings (security)				
Security Type *	0: open (no security/ encryption) 1: WEP 2: WPA_PSK (WPA with pre-shared key) 3: - 4: EAP**	0	N	Y

Manual v3.0, page 153 **Old:**

security_type	cipher_type	wep_auth_type	wep_key	wpa_key_type	wpa_key	wpa_passphrase
3 - WEP2	4 - WEP40	0 - open / 1 - shared	10 charac-ters HEX	-	-	-
3 - WEP2	5 - WEP40	0 - open / 1 - shared	26 charac-ters HEX	-	-	-

New:

security_type	cipher_type	wep_auth_type	wep_key	wpa_key_type	wpa_key	wpa_passphrase
3 -	-	-	-	-	-	-

(Setting “3” not used)

3.2 Additional information for chapter 3, “Patient Glucose Testing”

Obtaining a blood sample

Prepare the selected blood collection site and obtain blood from the patient per facility policy.

Recommendations for the collection of capillary blood

If no facility policy exists for obtaining capillary blood, the patient's hands (or heel in the case of small children) should be washed with warm water and soap, and then dried thoroughly. If you are using alcohol wipes or other disinfectants when obtaining capillary blood, the patient's skin must be completely dry before you lance the site to obtain blood.

We recommend obtaining the capillary blood sample from the side of the fingertip as this part is the least sensitive to pain.

WARNING

Potential risk of incorrect results due to residues on skin

- Traces of food on the fingers or fatty residues from hand creams or soap products may contaminate the sample and lead to incorrect results. Wash the puncture site thoroughly and rinse with plenty of water.
- Residues of water or disinfectant on the skin can dilute the drop of blood and lead to incorrect results. After you have washed and disinfected the site, ensure that the patient's skin is completely dry before lancing the site to obtain a capillary blood sample.

Use an auto-disabling single-use lancing device for each patient. The lancing device must be intended for use by healthcare professionals in a multiple patient setting. Follow the manufacturer's instructions for use.

3.3 Additional information for A Appendix “Example of barcode symbologies”

Manual v3.0, page 154

When creating patient or operator barcodes, always adhere to the applicable international IEC/ISO standards for the respective barcode symbology. In particular, ensure that barcode size and print quality (as defined in ISO/IEC 15421) are adequate. Inadequate print size and/or quality may lead to erroneous decoding.

EAN 13 barcodes, although widely used in retail, are not recommended for patient/operator barcodes. If used, they demand the very highest quality standards of barcode creation and reproduction.

The barcode samples shown on page 154 of Operator's Manual version 3.0 are for illustration purposes only. If printed out, they can be used to check the barcode scanner. However, they are not meant to be used as a reference for size or resolution of real patient or operator ID barcodes. Always refer to the relevant standard ISO/IEC 15421 for size and resolution requirements when creating patient or operator barcodes.

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