ACCU-CHEK® Inform II

Roche

Accu-Chek® Inform II

BLOOD GLUCOSE MONITORING SYSTEM

Supplement to the Operator's Manual v6

Changes from SW 04.02 to SW 04.03 and Amendments to Operator's Manual v6

ACCU-CHEK®

Revision History

Manual version	Revision date	Changes
Version 1.0	2018-11	New Document, created for SW 04.03 and as an amendment to Operator's Manual Version 6.0 for SW 04.02

Purpose of document

This document provides a description of changes to the Operator's Manual V6 for SW 04.03.00.

This supplement is valid for and intended to be used in conjunction with the Accu-Chek Inform II Operator's Manual version 6.0. It is not a replacement for the complete Accu-Chek Inform II Operator's Manual version 6.0.

Be sure to read the complete Accu-Chek Inform II Operator's Manual version 6.0.

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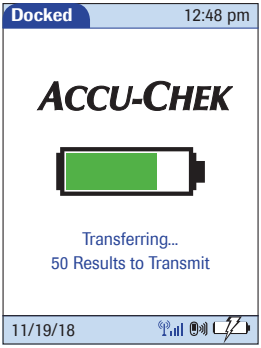
1 What is new in SW 04.03?

Battery status information in Docked and Diagnostics screens

Docked screen – battery status

Docking the meter in the base unit allows you to charge the battery pack. The *Docked* screen displays a large battery icon showing the current charging status of the battery. This information enables you to choose the meter with the best battery status for the next test.



Battery status is displayed as follows:

Icon	Description
	Battery is empty and device cannot be used.
	Test may be possible. Software updates and WLAN disabled.
	Normal use possible, only software updates disabled
	All functions available

Improved charging performance

After 2 minutes in the base unit, the meter powers off and goes into standby mode. The screen goes blank and the charging process starts. Charging the battery pack in standby mode improves charging performance.

When the screen is blank during the charging process, you can power on the meter at any time **to check** the battery charging status or that the meter is properly docked by touching the screen or pressing the On/Off button ⏻. The screen lights up for 2 minutes and displays the *Docked* screen with the colored battery icon best describing the current battery status.

If the meter is **NOT** properly docked, a short "humming" noise sporadically occurs and the battery charging icon  flashes in the status bar.

- Remove the meter from the base unit.
- Redock it by gently pushing it into the base unit to ensure proper contact.

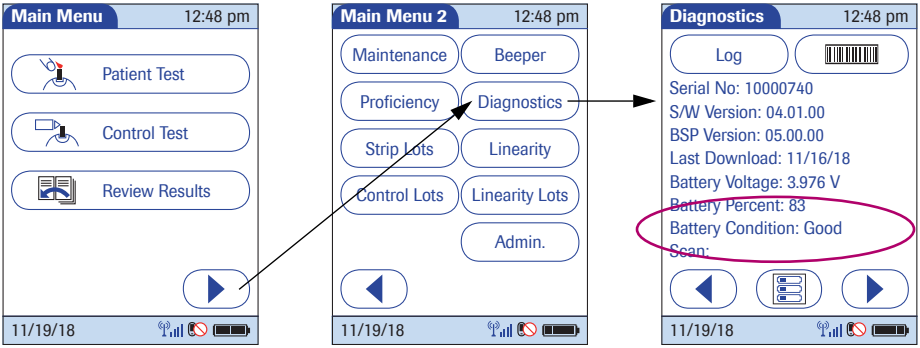
Once the meter is properly docked and charging, the battery charging icon stops flashing. See section "Low power icons" in Operator's Manual version 6.0 on page 153.

When the battery pack is fully charged, the meter powers on automatically and stays on. The screen displays the green battery icon to show that the battery is fully charged.

Diagnostics screen – battery condition

The cycle of battery charging, discharging, and recharging ages the battery. Over its lifespan, the battery pack will thus gradually loose capacity. This means, over time, it will power the meter for increasingly shorter periods of time.

In addition to the relative charging status indicated by the battery icon in the Docked screen, the meter provides information about the condition of the battery in the *Diagnostics* screen.



Battery Condition is displayed as follows:

- *Good*: capacity sufficient for normal usage
- *Limited*: capacity reduced due to battery aging

If a battery is no longer providing the expected performance and battery condition is displayed as *Limited*, contact your Roche Support Center.

New power management

Configurable automatic shutdown of undocked meter

SW 04.03 introduces a new configurable automatic shutdown feature that contributes to improving battery performance and extending battery lifespan.

Situation up to and including SW 04.02

When NOT docked, the meter powers itself off after a configurable time without activity (e.g., pressing a key, touching the screen) to conserve energy. Although the screen goes blank, the meter is in standby mode and continues to draw power from the battery pack to maintain date/time and run various functions in the background such as wireless communication. Thus in standby mode ("Automatic power off"), energy continues to be drawn from the battery and it depletes within a day if not docked.

For more information see sections titled "Power off meter", "Automatic power off", "Shut down meter", and "Automatic shutdown" in Accu-Chek Inform II Operator's Manual, version 6.0, pages 22-23.

New concept with SW 04.03

If the meter is manually shut down or shuts down due to a Download Lockout or because the battery pack is critically low, wireless communication and all other functionalities are shut down (although date and time are maintained).

SW 04.03 introduces a new power management concept. The meter can now be configured to automatically shut down 30 minutes after power-off when it is NOT docked. This feature is enabled by default.

With this new configurable automatic shutdown feature, the meter will automatically wake up on a regular basis for wireless communication. The setting for this wake-up timer is configurable in 1-minute steps starting from a base of 10 minutes. In other words, you can configure the meter to wake up every 10 minutes or every 11 minutes and so on up to once every 24 hours. It is possible to disable this wake-up timer by setting the interval value to "0" in the DMS. The default setting with SW 04.03 is every 30 minutes. (See configuration options in table on page 10.)

When you power up the meter from shutdown mode, it will take slightly longer than from power-off (standby) mode.

If you configure the meter to wake up more often from shutdown for wireless communication (if WLAN is enabled and the meter is not docked), more power will be drawn from the battery pack and the meter will need to be recharged more frequently. However, when you power up the meter, it is more likely to be synchronized. If you choose to leave the meter in shutdown until you power it up manually or opt for longer time intervals between waking up for wireless communication, the battery will last longer but synchronization with the DMS may also take longer. In this case however, the meter's database will probably need to be synchronized before you can start testing.

Which option you choose will be determined by the workflow needs of your institution.

Configuration options

Subject/Attribute	Range	Default	Device	DMS
Timer				
Power-off timeout (meter powers off automatically and goes into standby mode if no activity)*	30 – 3,600 s	300	N	Y
Shut down (meter automatically shuts down 30 minutes after powering off)	0: disabled 1: enabled	1	N	Y
Time Interval reconnect (0 = disabled)	0: disabled 10 – 1440 minutes (24 hrs)	30	N	Y
* Not applicable in measurement mode				

Improved barcode masking

Two additional options for barcode masking have been added:

- define a character type (numeric or non-numeric) that will be kept as part of the ID
- define separator characters to isolate the ID within barcode data of variable length

The complete barcode masking options are defined as follows:

Operator and patient ID barcode masks

Barcode mask character	Definition
A-Z/a-z, 0-9	If not preceded by the Caret ("^"), the scan data character must be the same as the mask character. This character is not saved as part of the ID. If the characters are not the same, the scan data is not a valid ID.
Dollar ("$")	The scan data character in this position is kept as part of the ID.
Asterisk ("*")	The scan data character in this position is not kept as part of the ID.
Tilde ("~")	The scan data character in this position must be a number, 0-9, and it is not kept as part of the ID. If the scan data character is not a number, the scan data is not a valid ID.
Plus ("+")	The scan data character in this position must be an alpha character, A – Z/a-z, and it is not kept as part of the ID. If the scan data character is not an alpha character, the scan data is not a valid ID.
Caret ("^")	This mask character denotes that the scan data character must be equal to the next character in the barcode mask after the "^", and that the scan data character is kept as part of the ID. If the scan data character is not equal to the mask character following the "^", the barcode reading is invalid as an ID.
Caret Plus ("^+")	The "^" can be combined with the plus ("+"). This denotes that the scan data character in this position must be an alpha character, A – Z/a-z, and that it is kept as part of the ID. If the scan data character is not an alpha character, the scan data is not a valid ID.
Caret Tilde ("^~")	The "^" can be combined with the tilde ("~"). This denotes that the scan data character in this position must be a number, 0-9, and that it is kept as part of the ID. If the scan data character is not a number, the scan data is not a valid ID.

The barcode mask can be preceded by optional square brackets containing the separator characters - [nC_1mC_2] - to extract the ID from any position within the barcode. The ID to be extracted must start after the n^{th} occurrence of the starting character C_1 and must end after the m^{th} occurrence of the ending character C_2. The extracted string of characters will be processed by the succeeding mask (see page 11) to identify the patient ID.

C_1 and C_2 can be represented by any readable characters, or by any hexadecimal ASCII values if marked by a preceding backslash ("\"). See the table of ASCII characters on page 24.

Example 1:

[1$1+]^+^~^~^~^~^~^~^~

Extract the ID between first occurrence of "$" and first occurrence of "+". The ID must start with one alpha character (A-Z/a-z), followed by seven numbers (0-9). This mask will extract the ID X1234567 from the following barcode example:

```
~Jane Doe%$X1234567+5715486266Z?01-09-1979
```

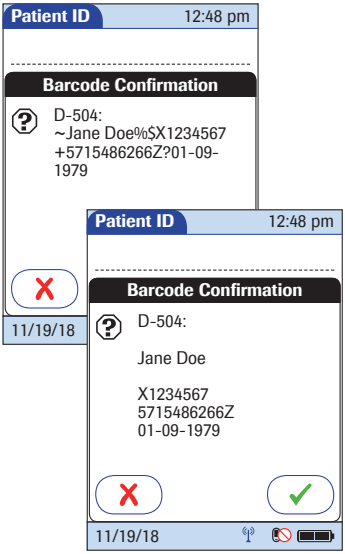
Example 2:

[3\3b1\3b]^+^~^~^~^~^~^~^~

Extract the ID between 3rd and 4th semicolon (; = 0x3b). This mask will extract the ID X1234321 from the following barcode example:

```
;Mary Miller;;X1234321;5715486266Z;01-09-1982
```

Add barcode content to a result



With SW 04.03 it is now possible to read and display the complete content of a barcode (not only the extracted ID) and add it as a comment to the test result, to be further processed by the DMS. This option can only be configured via a DMS. The following options can be set:

- Barcode content will not be added to the result
- Barcode content will be added to the result
- Barcode content will be displayed for confirmation after scanning and then added to the result

If the meter is set to the last option (enabled with confirmation), you can choose to display the complete barcode content in the confirmation screen as follows:

- The barcode is displayed as a continuous string of characters without any formatting. The separator characters ("~%$+?") are shown. See example in top screen in the illustration on the left.
- The barcode is divided into separate lines for easier reading. The separator characters ("~%$+?") are replaced by line breaks. See example in the bottom screen in the illustration on the left.

The replacement of separator characters by line breaks is only applied temporarily for display in the *Barcode Confirmation* screen. The barcode information stored with the test result contains the original separator characters.

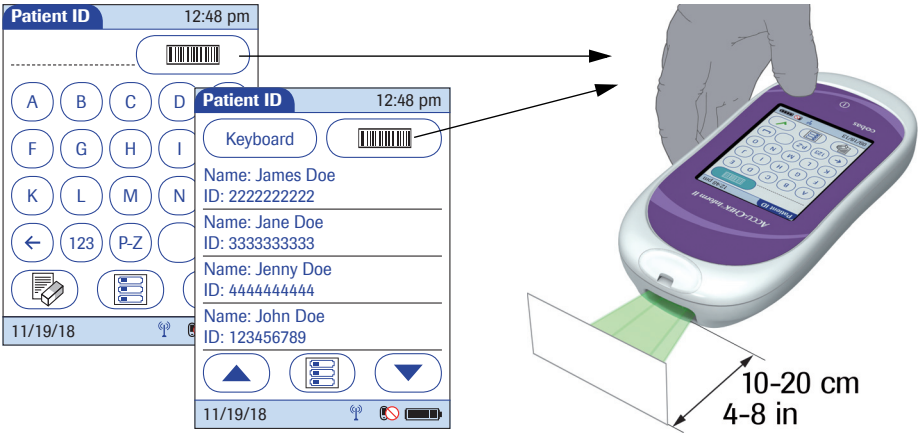
During a patient test, the *Barcode Confirmation* screen appears before the *Patient Confirmation* screen, if both are enabled.

Configuration options

Subject/Attribute	Range	Default	Device	DMS
Barcode Configuration				
Add barcode to patient test result	0: disabled 1: enabled 2: enabled and confirm	0	N	Y
Barcode Separators: List of separator characters (readable characters, or hexadecimal ASCII values* preceded by a backslash) to be replaced by line breaks on the confirmation screen. Only valid if *Add barcode to patient test result*=2.	0-30 characters	""	N	Y
* See the table of ASCII characters on page 24.				

Entering a patient ID with barcode scanner

When the screen for entering the patient ID is displayed:



1 Press and release . The button now appears with a black background (during the scan).

2 Hold the meter so that the window of the barcode scanner is approx. 10-20 cm (4-8 in) above the barcode you wish to read.

The meter beeps once the barcode has been read successfully.

3 If the function *Patient Confirmation* is enabled, verify and confirm the complete unmasked barcode information.

The extracted patient ID[1] appears in the patient ID field of the succeeding screens. The barcode scanner turns off after 10 seconds if a barcode is not scanned.

1. See also section “Improved barcode masking” in this supplement, starting on page 11.

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.

Configuration options

Subject/Attribute	Range	Default	Device	DMS
Electronic communication				
TLS Encryption of WLAN communication	0: disabled 1: enabled	0	N	Y

2 Amendments to Operator's Manual version 6.0

Revised sections

9.2 Installing or replacing the battery pack

The following information has been added on page 121:

Replace the battery pack within approximately 10 minutes to retain the date and time settings. Beyond this period of time, you may have to re-enter date and time. Replace the battery pack only in shutdown mode, see page 122.

Data stored in the memory (see section 12.1 of the Operator's Manual) is not lost when replacing the battery pack even if no battery is inserted for a longer period of time. All settings (other than date/time - see above) are also retained.

12.1 Technical data

The following revisions have ben made on page 159:

Specification	Meter	Base unit	Power supply unit
Battery voltage/type	3.7 volt rechargeable (lithium technology)	N/A	N/A
Input voltage	+7.5 V DC	Base Unit: +12 V DC legacy Base Unit Light: +7.5 V DC NEW Base Unit Light: +12V DC	100 to 240 V AC
Input frequency	DC	DC	50 to 60 Hz
Input current	1.7 A (max)	Base Unit: 1.25 A (max) legacy Base Unit Light: 1.7 A (max) NEW Base Unit Light: 1.25 A (max)	350 to 150 mA (REF 07006098001, 07455976190) 400 to 150 mA (REF 08692432001, 08692432160)
Battery capacity	30 (subsequent) measurements possible after 90 min of charging[1]	N/A	N/A
Interfaces	Charging contacts IR port Barcode scanner WLAN (Channel 1-11 only)	Charging contacts IR port RJ45 Ethernet (Base Unit) RJ25 (Base Unit Light) USB type B *	DC connector Replaceable AC input contacts

1. A fully charged battery pack will provide sufficient power for at least 100 tests within 5 hours including wireless communication (WLAN, if available and enabled).

Specification	Meter	Base unit	Power supply unit
Data transfer rate	WLAN: up to 54 Mbps	IR: 9.6K - 115K bps [1] Ethernet: 10/100 Mbps (auto-negotiate) full-duplex [1] USB: 12 Mbps [1]	N/A
		In combination with the Base Unit Hub: IR: 9.6K - 115K bps[2] Ethernet: 10 Mbps half-duplex[3]	
Supported barcodes	Code 128, Code 39, Code 93, EAN 13, Interleaved 2 of 5 (with or without checksum), Codabar, GS1 DataBar Limited, Aztec, QR Code, DataMatrix, PDF417	N/A	N/A

1. Accu-Chek Inform II Base Unit
2. Accu-Chek Inform II Base Unit Light (NEW and legacy versions)
3. Accu-Chek Inform II Base Unit Hub

12.2 Further Information - Ordering

Changes to the ordering information in the Accu-Chek Inform II Operator's Manual version 6.0 (page 163) are shown in red.

Item	Description	REF/Catalog Number
Accu-Chek Inform II Meter	Meter, equipped with built-in WLAN functionality	05060303001
Accu-Chek Inform II Battery Pack	Rechargeable battery pack (for meters with serial no. above UU14000000)	06869904001
Accu-Chek Inform II Battery Compartment Cover	Replacement cover for meter battery compartment (for meters with serial no. above UU14000000)	06869823001
Accu-Chek Inform II Base Unit (NEW)	Equipped with charging and connectivity functionality	07671717190
Accu-Chek Inform II Base Unit Light (NEW)	Equipped with charging functionality	08376824190
Power Supply*	Power supply (international edition) for Base Unit Light (NEW) REF 08376824190/ Base Unit (NEW) REF 07671717190	07006098001
Power Supply*	Power supply (North America) for Base Unit Light (NEW) REF 08376824190/ Base Unit (NEW) REF 07671717190	07455976190

* **Important note**

Power supply REF 07006098001, (International edition) and Power supply REF 07455976190, (North America), Type: FW7555M/12, Input: 100-240V/50-60Hz/350-150 mA, Output: 12V ⎓ 1.25A will be discontinued and replaced by:

Power supply REF 08692432001, (International edition) and Power supply REF 08692432160, (North America), Type: FW8001M/12, Input: 100-240V/50-60Hz/400-150 mA, Output: 12V ⎓ 1.50A

The change in power supply has no effect on product performance. Type: FW7555M/12 and Type: FW8001M/12 can be used in parallel.

Item	Description	REF/Catalog Number
Accu-Chek Inform II Base Unit Light (legacy version)	Equipped with charging functionality (discontinued)	05920353001
Power Supply	Power supply (international edition) for legacy Base Unit Light REF 05920353001/ legacy Base Unit REF 05060290001	04805666001
Power Supply	Power supply (North America) for legacy Base Unit Light REF 05920353001/ legacy Base Unit REF 05060290001	05388805001
Accu-Chek Inform II Base Unit Wall Mount	Wall Mount for Base Unit/Base Unit Light (fits legacy and new versions)	05404878001
Accu-Chek Inform II Base Unit Hub	Equipped with power and connectivity functionality for the Accu-Chek Inform II Base Unit Light	05888760001
Power Cord	Required to power the Base Unit Hub (North America)	03868133001
Power Cord	Required to power the Base Unit Hub (United Kingdom)	03034933001
Power Cord	Required to power the Base Unit Hub (international)	11800515001
Accu-Chek Inform II Code Key Reader		04884671001
Accu-Chek Inform II Accessory Box		05060281001
Accu-Chek Inform II Battery Pack	Rechargeable battery pack (for meters with older hardware and serial no. below UU14000000)	04882326001
Accu-Chek Inform II RF Card Kit	Wi-Fi card replacement (for meters with older hardware and serial no. below UU14000000)	05112699001

A1 Table of configuration options

The following configuration option is available as of software version 04.02. The following addition has been made on page 171:

Subject/Attribute	Range	Default	Device	DMS
Measurement Flow				
Isolation Room	0: disable (select patient ID before strip lot selection) 1: enable (select strip lot before patient ID selection)	0	N	Y
Configurable QC Lockout (when switching strip lot)	0: disabled 1: enabled	1	N	Y

The following revisions have been made on page 173:

Subject/Attribute	Range	Default	Device	DMS
Operator ID				
Operator ID validation (Any character allowed [except non-printable ones, represented as hexadecimal ASCII values by 0x01 - 0x1F and 0x7F]. Via the meter keyboard only A-Z/a-z, 0-9, "." [period], "-" [hyphen] can be entered.) Remark: leading and trailing spaces are truncated.	0: none 1: length 2: list 3: list & password	0	Y	Y

The following revisions have been made on page 174:

Subject/Attribute	Range	Default	Device	DMS
Patient ID				
Patient ID validation (Any character allowed [except non-printable ones, represented as hexadecimal ASCII values by 0x01 - 0x1F and 0x7F]. Via the meter keyboard only A-Z/a-z, 0-9, "." [period], "-" [hyphen] can be entered.) Remark: leading and trailing spaces are truncated.	0: none 1: length 2: list 3: list allowing entry if not on list 4: length if numeric	0	Y	Y

B.1 Option: Wireless network (WLAN)

The following addition has been made on page 187:

Note: For technical reasons, only client certificates in a *.pem file format are acceptable for EAP-TLS authentication. In a Windows-based network environment, *.pfx files need to be converted to *.pem format. It is in the responsibility of the customer / customer's IT department to convert *.pfx certificates to the required *.pem format.

Appendix: Table of ASCII characters

Dec	Hex	Char	Dec	Hex	Char	Dec	Hex	Char	Dec	Hex	Char
0	0	[NULL]	32	20	[SPACE]	64	40	@	96	60	`
1	1	[START OF HEADING]	33	21	!	65	41	A	97	61	a
2	2	[START OF TEXT]	34	22	"	66	42	B	98	62	b
3	3	[END OF TEXT]	35	23	#	67	43	C	99	63	c
4	4	[END OF TRANSMISSION]	36	24	$	68	44	D	100	64	d
5	5	[ENQUIRY]	37	25	%	69	45	E	101	65	e
6	6	[ACKNOWLEDGE]	38	26	&	70	46	F	102	66	f
7	7	[BELL]	39	27	'	71	47	G	103	67	g
8	8	[BACKSPACE]	40	28	(	72	48	H	104	68	h
9	9	[HORIZONTAL TAB]	41	29	)	73	49	I	105	69	i
10	A	[LINE FEED]	42	2A	*	74	4A	J	106	6A	j
11	B	[VERTICAL TAB]	43	2B	+	75	4B	K	107	6B	k
12	C	[FORM FEED]	44	2C	,	76	4C	L	108	6C	l
13	D	[CARRIAGE RETURN]	45	2D	-	77	4D	M	109	6D	m
14	E	[SHIFT OUT]	46	2E	.	78	4E	N	110	6E	n
15	F	[SHIFT IN]	47	2F	/	79	4F	O	111	6F	o
16	10	[DATA LINK EXCAPE]	48	30	0	80	50	P	112	70	p
17	11	[DEVICE CONTROL 1]	49	31	1	81	51	Q	113	71	q
18	12	[DEVICE CONTROL 2]	50	32	2	82	52	R	114	72	r
19	13	[DEVICE CONTROL 3]	51	33	3	83	53	S	115	73	s
20	14	[DEVICE CONTROL 4]	52	34	4	84	54	T	116	74	t
21	15	[NEGATIVE ACKNOWLEDGE]	53	35	5	85	55	U	117	75	u
22	16	[SYNCHRONOUS IDLE]	54	36	6	86	56	V	118	76	v
23	17	[ENG OF TRANS. BLOCK]	55	37	7	87	57	W	119	77	w
24	18	[CANCEL]	56	38	8	88	58	X	120	78	x
25	19	[END OF MEDIUM]	57	39	9	89	59	Y	121	79	y
26	1A	[SUBSTITUTE]	58	3A	:	90	5A	Z	122	7A	z
27	1B	[ESCAPE]	59	3B	;	91	5B	[	123	7B	{
28	1C	[FILE SEPARATOR]	60	3C	<	92	5C	\	124	7C	|
29	1D	[GROUP SEPARATOR]	61	3D	=	93	5D	]	125	7D	}
30	1E	[RECORD SEPARATOR]	62	3E	>	94	5E	^	126	7E	~
31	1F	[UNIT SEPARATOR]	63	3F	?	95	5F	_	127	7F	[DEL]

Notes

Notes

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0 8818703001 (01) 2018-11 EN-CAN

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