

ACCU-CHEK[®] *Inform II*

Operator's Manual

Base Unit HUB



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Roche Diagnostics
Commercial Education Department
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457
USA

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On the packaging, on the back label of the instrument and in the manual you may encounter the following symbols, shown here with their meaning:

LOT

Lot number

IVD

For *in vitro* diagnostic use

CE

This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices.

REF

Catalog number



Please consult instructions for use.



Caution (refer to accompanying documents). Please refer to safety-related notes in the manual accompanying this instrument.



Manufacturer



Store at

Revision History

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If you need technical help, call ACCU-CHEK® Customer Care Service Center at 1-800-440-3638, 24 hours a day, 7 days a week, 365 days a year.

INTRODUCTION

Indications for use

The ACCU-CHEK® Inform II Base Unit HUB is intended for use as an accessory to the ACCU-CHEK Inform II System. The ACCU-CHEK Inform II Base Unit HUB transfers data from the ACCU-CHEK Inform II Base Unit Light and docked ACCU-CHEK Inform II meter to a data management system as an aid in monitoring the effectiveness of glucose control. The ACCU-CHEK Inform II system is meant for *in vitro* diagnostic use by healthcare professionals in clinical settings.

This system is limited to healthcare professional use only.

Contents of the pack

- 4 serial cables with RJ-25 connectors on both sides
- Base Unit HUB
- USB cable
- Power supply (*adapter provided separately*)

Safety information

Caution: Operator qualification

Only trained healthcare professionals may operate the ACCU-CHEK Inform II system. The system includes the ACCU-CHEK Inform II Base Unit HUB. The system can include or may include the ACCU-CHEK Inform II Base Unit or the ACCU-CHEK Inform II Base Unit Light. Operators must also have received comprehensive instruction in the operation, quality control and care of the ACCU-CHEK Inform II system.

Be sure to read the Important Safety Instructions and Additional Information section in chapter 1 of the ACCU-CHEK Inform II Operator's Manual before operating the system for the first time.

NOTE: *The ACCU-CHEK Inform II Base Unit HUB may only be used in combination with the ACCU-CHEK Inform II Base Unit Light and not with the ACCU-CHEK Inform II Base Unit.*

Operating conditions

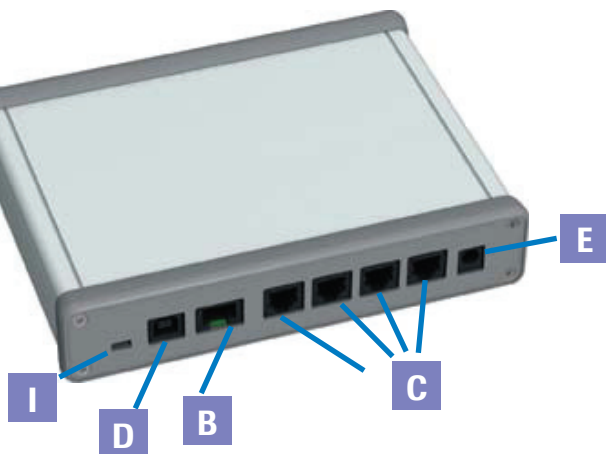
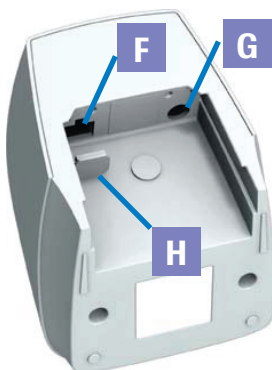
To ensure that your ACCU-CHEK Inform II Base Unit HUB functions properly, observe the following guidelines:

- Only use the device at a room temperature between 37 °F and 122 °F (3 °C and 50 °C).
- Use only mains voltage of 100V to 240 V ($\pm 10\%$), 50/60 Hz.
- Use only the standard 12V cabled power supply for medical use.

Caution: Electromagnetic interference

The ACCU-CHEK Inform II system complies with both the electromagnetic immunity requirements and radio interference immunity requirements at the frequency and test levels according to EN ISO 15197 Annex A. The system also complies with the electrostatic discharge (ESD) immunity requirements as specified in IEC 61000-4-2 and complies with applicable electromagnetic emissions (EMC) requirements according to EN 61236. The system's emissions of the energy used are low and not likely to cause interference in nearby electronically driven equipment.

Electrostatic Discharge (ESD) is an electrical charge at rest, most commonly known as static electricity. To avoid ESD, do not use the meter in a very dry environment, particularly one in which synthetic materials (e.g., carpets) are present that might cause damaging static discharges, or near electronic equipment that is a source of electromagnetic radiation.

Base Unit HUB*Front view***Base Unit HUB***Back view***Base Unit Light***Back view*

THE ACCU-CHEK INFORM II BASE UNIT HUB SYSTEM

Device elements overview

A

LED

Light indicating the device status.

ACCU-CHEK Inform II Base Unit HUB status display

- Lights up red: Power supply is connected, application is starting up
- Lights up green: Ready
- Flashes red (once per second): Error
- Lights up blue: Configuration mode

B

Ethernet/RJ45 connector

Used for remote configuration and communication

C, F

RJ25 connectors

Used for communication and alternative power supply on both the ACCU-CHEK Inform II Base Unit HUB (**C**) and the ACCU-CHEK Inform II Base Unit Light (**F**).

D

USB

Used for local configuration

Connection ports

The following connection ports are located on the back of the ACCU-CHEK Inform II Base Unit HUB and the ACCU-CHEK Inform II Base Unit Light:

B, D

Data ports—USB (**D**) and Ethernet (**B**) ports for connecting the device to a host computer

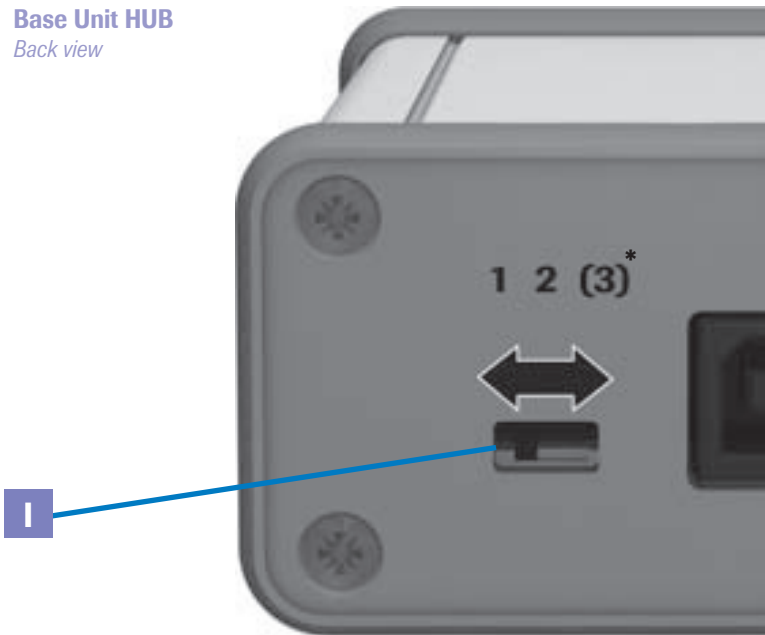
E, G

Power adaptor—Plug in the power supply here: (**E**) on the ACCU-CHEK Inform II Base Unit HUB and (**G**) on the ACCU-CHEK Inform II Base Unit Light.

NOTE: *The ACCU-CHEK Inform II Base Unit Light does not require a power supply cord when connected to the ACCU-CHEK Inform II Base Unit HUB.*

Base Unit HUB

Back view



** Option 3 is not applicable as a communication mode for the ACCU-CHEK Inform II Base Unit HUB.*

H Removable connector cover

Used for the RJ25 connector (ACCU-CHEK Inform II Base Unit Light(s) only)

I Mode switch

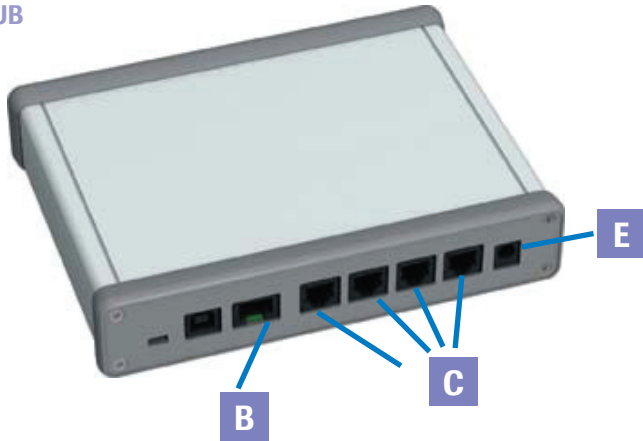
A switch (USB configuration switch), on the back of the ACCU-CHEK Inform II Base Unit HUB and under the plastic cover, sets the ACCU-CHEK Inform II Base Unit HUB to one of two different modes of operation.

Position	Mode	Description
1	Configuration	The Base Unit HUB acts as a mass storage device on the USB port. This method of communication with the Base Unit HUB includes writing and reading files using a mounted file system.
2	Serial (ICI) and Ethernet (POCT1-A)	Communication via Ethernet -or- The Base Unit HUB converts meter communication (IrDA) received on the IR window of the Base Unit HUB to wired Ethernet. Note: The Base Unit HUB cannot handle Serial and Ethernet conversion simultaneously. Both communication paths will be handled one after the other by means of timeouts.

Note: The position of the switch may be changed while the ACCU-CHEK Inform II Base Unit HUB is powered.

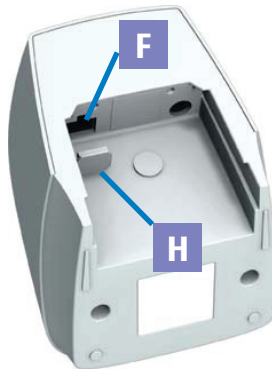
Base Unit HUB

Back view



Base Unit Light

Back view



Power supply

The power cord supplied with the ACCU-CHEK Inform II Base Unit Light can be operated with the power adaptor provided with the ACCU-CHEK Inform II Base Unit HUB. The power supply can also be ordered separately.

The power supply and adaptor must be connected to create a power supply cord. The power supply cord connects to the ACCU-CHEK Inform II Base Unit HUB and power outlet to create power and functionality of the system.

Caution: *For continued safety and reliability, use only the power supply provided with your system or ordered from Roche.*

Operating the device

1. Connect the power supply to the power adapter (E). Then connect the the power cord to the ACCU-CHEK Inform II Base Unit HUB and the outlet.
2. Connect an Ethernet / RJ-45 cable to the back of the ACCU-CHEK Inform II Base Unit HUB (B) and to an RJ-45 network outlet.
3. Once the ACCU-CHEK Inform II Base Unit HUB has power, connect it to a ACCU-CHEK Inform II Base Unit Light(s):
 - a. Remove the connector cover (H) on the ACCU-CHEK Inform II Base Unit Light(s), using a small screwdriver or similar tool.
 - b. Plug the RJ25 cable (provided with the ACCU-CHEK Inform II Base Unit HUB) to the RJ25 port (F) on the ACCU-CHEK Inform II Base Unit Light(s).
 - c. Connect the other end of the cable to one of the RJ25 ports (C) available on the ACCU-CHEK Inform II Base Unit HUB.

Note: *Differences between Ethernet or RJ-45 and RJ-25 cables.*

- *An RJ45 uses 8 wires and 8 contacts for connection in Ethernet network.*
- *An RJ25 uses 6 wires using 6 contacts for connection and cannot be plugged into an RJ-45 port for connectivity.*

Caution: *Use only the RJ25 cable provided with the ACCU-CHEK Inform II Base Unit HUB.*

To help the System Administrator configure the ACCU-CHEK Inform II Base Unit HUB, technical documentation is provided. This technical note is stored on the ACCU-CHEK Inform II Base Unit HUB itself as a PDF file. You can access this file by connecting the ACCU-CHEK Inform II Base Unit HUB (D) to a PC with the USB cable.

Caution: *Use only the USB cable provided with the ACCU-CHEK Inform II Base Unit HUB.*

Note: *For the ACCU-CHEK Inform II Base Unit HUB, you should plug in either a USB cable or an Ethernet cable, but not both at the same time.*

Note: *When the ACCU-CHEK Inform II Base Unit Light is connected to the ACCU-CHEK Inform II Base Unit HUB via an RJ25 cable, remove the power supply connector from the ACCU-CHEK Inform II Base Unit Light. Power is provided by the ACCU-CHEK Inform II Base Unit HUB via the RJ25 connection.*

Note: *Up to four ACCU-CHEK Inform II Base Unit Lights can be utilized.*

Important notes

Always...

- ...handle the device carefully; avoid dropping or bumping it
- ...operate the device at an ambient temperature between 37 °F and 122 °F (3 °C and 50 °C).
- ...place the device on a level, stable surface (such as a table)
- ...keep the device clean

Never ...

- ...spill liquids on the device
- ...immerse the device in any liquid
- ...expose the device to excessive sources of heat for a prolonged time
- ...store the device in damp or humid conditions without protection
- ...touch the charging terminals with metallic items, such as a paper clip, during operation

Self test

The ACCU-CHEK Inform II Base Unit HUB performs a self test at regularly scheduled intervals. The self test requires that the ACCU-CHEK Inform II Base Unit HUB software reboot. To avoid interrupting communication between the meter and ACCU-CHEK Inform II Base Unit HUB, the software will only self test and reboot when communication has been idle for at least 10 minutes. The test procedure itself takes about 3 minutes—in this time no communication between the meter and the host computer is possible. During the self-test phase, the HUB LED indicator turns from green (ready) to red (not ready). After the self test the ACCU-CHEK Inform II Base Unit HUB will return automatically back to the configuration and state it was in before the self test and the LED will turn green.

As part of the self test, the integrity of the ACCU-CHEK Inform II Base Unit HUB's internal memory is checked. In case of a failure, the LED flashes red and the base will stay in configuration mode even if the mode switch is set to a different position; no USB or Ethernet communication will be possible.

CLEANING

Cleaning the Base Unit HUB

Use the following procedure to clean the ACCU-CHEK Inform II Base Unit HUB:

1. Place the base unit on a level surface prior to cleaning.
2. Unplug the ACCU-CHEK Inform II Base Unit HUB.
3. Remove a Clorox Germicidal Wipe from its packaging. Squeeze the wipe out and blot on a dry paper towel to remove any excess solution from it.
4. Use a Clorox Germicidal Wipe to clean by gently wiping the surfaces of the base unit light being careful to remove any visible soil or organic material. Use additional wipes as needed. NOTE: Do not wipe the electrical connectors on the back of the base unit
5. Dry the base unit surfaces thoroughly with a soft cloth or gauze after cleaning. Visually verify that no solution is seen anywhere on the base unit at the completion of cleaning.

NOTICE Ensure the ACCU-CHEK Inform II Base Unit HUB (including connectors) is thoroughly dried after cleaning or disinfecting. A flashing LED (red) on the ACCU-CHEK Inform II Base Unit HUB indicates a fault condition.

NOTICE Do not spray the ACCU-CHEK Inform Base Unit HUB directly with solutions as this could cause the solution to enter the case and damage the electronic components.

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PRODUCT SPECIFICATION

Operating conditions and technical data

Temperature range	37 °F to 122 °F (3 °C to 50 °C).
Position	Place the ACCU-CHEK Inform II Base Unit Hub on a level surface (such as a table)
Interfaces	Ethernet (TCP/IP)
Height	1.3 in.
Width	6.5 in.
Length	6.5 in.
Weight	28.2 oz.

Storage and transport conditions

Temperature range	41 °F to 104 °F (5 °C to 40 °C).
Relative humidity	10 to 85% (non condensing)

TROUBLESHOOTING

Display/ symptom	Root cause	Possible solution
LED is not on	Not connected to power supply or power supply is defective, the ACCU-CHEK Inform II Base Unit HUB is defective, or power outlet not active.	Disconnect and connect the power supply again. Try another outlet.
LED flashes red	Communication or configuration error.	Check the configuration and/or the connection to the Data Management System (DMS). Contact the DMS or IT administrator of your institution.

If the error persists, call ACCU-CHEK[®] Customer Care Service Center at 1-800-440-3638, 24 hours a day, 7 days a week, 365 days a year.

INFORMATION ABOUT THE SOFTWARE LICENSE

This product incorporates software that is under license from GPL. The source code for this software can be requested from the following address:

Roche Diagnostics GmbH, Sandhofer Str. 116, D-68305 Mannheim

The GPL licensing conditions are printed in the ACCU-CHEK Inform II User Manual. (in English only for legal reasons): GPL, Version 2, June 1991

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WARRANTY

ACCU-CHEK Inform II Base Unit HUB Limited (1 Year) Warranty

ROCHE DIAGNOSTICS warrants, to the original purchaser only, that the Base Unit HUB shall be free from all defects in material and workmanship for a period of one year from the date of purchase. Purchaser's sole and exclusive remedy, with respect to the Base Unit HUB and parts thereof, shall be the repair and/or replacement of the Base Unit HUB or parts at the option of Roche Diagnostics.

THE ABOVE WARRANTY IS EXCLUSIVE OF ALL OTHER WARRANTIES, AND ROCHE DIAGNOSTICS MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE TO THE PURCHASER OR ANY OTHER PERSON FOR ANY INCIDENTAL, CONSEQUENTIAL, INDIRECT, SPECIAL OR PUNITIVE DAMAGES ARISING FROM OR IN ANY WAY CONNECTED WITH THE PURCHASE OR USE OF THE BASE UNIT HUB. NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, IF ANY IS IMPLIED FROM THE SALE OF THE BASE UNIT HUB, SHALL EXTEND FOR A LONGER DURATION THAN ONE YEAR.

The foregoing warranty shall not apply to a Base Unit HUB which is damaged by accident or subject to alteration, misuse, tampering, and/or abuse, including the use of Dispatch® products. Base Unit HUBs which show damage or misuse will be handled in accordance with Roche Diagnostics' non-warranty service policy. The warranty of the repaired/replacement Base Unit HUB will expire on the date of the original warranty expiration or ninety (90) days after shipment of a replacement Base Unit HUB, whichever period is longer.

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Roche Diagnostics GmbH
D-68298 Mannheim
Germany

Distributed by:
Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46256 USA

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