Digitally signed by Dolgopol Iulian
Date: 2024.10.07 11:14:25 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

STATEMENT

We, ACON Laboratories, Inc., having a registered office at *5850 Oberlin Drive #340, San Diego, CA 92121* authorize SRL Sanmedico having a registered office at *A. Corobceanu street 7A, apt. 9, Chisinău, MD-2012, Moldova*

to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Date: March 18, 2024

Signature: _____

Qiyi Xie, Md, MPH
V.P. of Regulatory & Clinical Affairs
ACON Laboratories, Inc.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 104507 0003 Rev. 06

Manufacturer: **ACON Laboratories, Inc.**
5850 Oberlin Drive, #340
San Diego CA 92121
USA

Product Category(ies): **Blood glucose measuring systems for self testing and self-testing devices for clinical chemistry, hematology and pregnancy and ovulation**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V1 104507 0003 Rev. 06

Report no.: SH22743EXT01

Valid from: 2022-05-04
Valid until: 2025-05-26

Date, 2022-05-04

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 104507 0003 Rev. 06

Model(s):

On Call Plus Blood Glucose Monitoring System,
On Call Plus Blood Glucose Test Strips,
On Call EZ II Blood Glucose Monitoring System,
On Call Advanced Blood Glucose Monitoring System,
On Call Advanced Blood Glucose Test Strips,
On Call Chosen Blood Glucose Test Strips,
On Call Vivid Blood Glucose Monitoring System (OGM-101),
On Call Vivid Blood Glucose Test Strips (OGS-101),
On Call Sharp Blood Glucose Monitoring System (OGM-121),
On Call Sharp Blood Glucose Test Strips (OGS-121)
On Call Plus II Blood Glucose Monitoring System (OGM-171),
On Call Plus II Blood Glucose Test Strips (OGS-171),
On Call Extra Blood Glucose Monitoring System (OGM-191),
On Call Extra Blood Glucose Test Strips (OGS-191),
On Call GK Dual Blood Glucose & Ketone Monitoring System (OGM-161),
On Call Blood Ketone Test Strips (OGS-161),
Urinalysis Reagent Strips (Urine),
UTI Urinary Tract Infection Test Strips,
Cholesterol Monitoring System (CCM-111),
CHOL Total Cholesterol Test Devices (CCS-111),
TRIG Triglycerides Test Devices (CCS-112),
HDL High Density Lipoprotein Test Devices (CCS-113),
3-1 Lipid Panel Test Devices (CCS-114),
Cholesterol CTRL Control Devices,
Cholesterol Monitoring System (CCM-101),
CHOL Total Cholesterol Test Strips (CCS-101),
PT/INR Monitoring System (CCM-151),
PT/INR Test Strips (CCS-151),
Hemoglobin Testing System (CCM-141),
Hemoglobin Test Strips (CCS-141),
hCG Pregnancy Rapid Test Cassette (Urine),
Pregnancy Rapid Test Midstream,
On Call Extra Mobile Blood Glucose Monitoring System (OGM-281),
On Call Sure Blood Glucose Monitoring System (OGM-211),
On Call Sure Sync Blood Glucose Monitoring System (OGM-212),
On Call Sure Blood Glucose Test Strips (OGS-211),
GIMA Blood Glucose Monitoring System,
GIMA Bluetooth Blood Glucose Monitoring System,
GIMA Blood Glucose Test Strips,
On Call GU Dual Blood Glucose & Uric Acid Monitoring

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 104507 0003 Rev. 06

System (OGM-201),
On Call Blood Uric Acid Test Strips (OGS-201),
LH Ovulation Rapid Test Cassette (Urine),
Ovulation Rapid Test Midstream,
Ovulation & Pregnancy Test Combo Pack,
On Call Extra Voice Blood Glucose Monitoring System (OGM-291),
Early Detection Pregnancy Test,
Digital Pregnancy Test,
Go-Keto Blood Glucose & Ketone Monitoring System (OGM-161),
Go-Keto Blood Ketone Test Strips (OGS-161),
Go-Keto Blood Glucose Test Strips,
On Call Extra GM Blood Glucose Monitoring System(OGM-191),
On Call Extra GM Blood Glucose Test Strips (OGS-191),
On Call Plus GM Blood Glucose Monitoring System,
On Call Plus GM Blood Glucose Test Strips,
Go-Keto Urinalysis Reagent Strips

Facility(ies):

ACON Laboratories, Inc.
5850 Oberlin Drive, #340, San Diego CA 92121, USA

ACON Laboratories, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

AZURE Institute, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

Acon Laboratories Inc.
Guerrero Negro 9942 Parque Industrial Pacifico IV, 22644 Tijuana B.C. CP, MEXICO

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TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 104507 0001 Rev. 03

Holder of Certificate: **ACON Laboratories, Inc.**
5850 Oberlin Drive, #340
San Diego CA 92121
USA

Certification Mark:

Scope of Certificate: **Design and Development, Manufacture and distribution of In Vitro Diagnostic Test Kits and Reagents for the Determination of Infectious Diseases, Clinical Chemistry, Drugs of Abuse, Tumor/Cardiac Marker, Fertility/Pregnancy and Blood Glucose Monitoring System, Lancing Devices and Lancets**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 104507 0001 Rev. 03

Report No.: SH22743A01

Valid from: 2022-09-15
Valid until: 2025-09-06

Date, 2022-09-15

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 104507 0001 Rev. 03

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

ACON Laboratories, Inc.
5850 Oberlin Drive, #340, San Diego CA 92121, USA

Address holder for registration only

ACON Laboratories, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

Manufacture and distribution of
In Vitro Diagnostic Test Kits and Reagents for the Determination of Infectious Diseases, Clinical Chemistry, Drugs of Abuse, Tumor/Cardiac Marker, Fertility/Pregnancy and Blood Glucose Monitoring System, Lancing Devices and Lancets

ACON Laboratories, Inc.
6865 Flanders Dr., Suite B, San Diego CA 92121, USA

Storage of
In Vitro Diagnostic Test Kits and Reagents for the Determination of Infectious Diseases, Clinical Chemistry, Drugs of Abuse, Tumor/Cardiac Marker, Fertility/Pregnancy and Blood Glucose Monitoring System, Lancing Devices and Lancets

AZURE Institute, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

Design and Development of
In Vitro Diagnostic Test Kits and Reagents for the Determination of Infectious Diseases, Clinical Chemistry, Drugs of Abuse, Tumor/Cardiac Marker, Fertility/Pregnancy and Blood Glucose Monitoring System, Lancing Devices and Lancets

Acon Laboratories Inc.
Guerrero Negro 9942 Parque Industrial Pacifico IV, 22644
Tijuana B.C. CP, MEXICO

Manufacture of
blood glucose test strips, antigen rapid test and IgG/IgM antibody rapid test for infectious disease.

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ACON Laboratories, Inc.
10125 Mesa Rim Road. · San Diego, CA 92121 · USA
Tel: (858) 875-8000 · Fax: (858) 875-8099 · E-mail: info@aconlabs.com

November 11th 2016

CERTIFICATION LETTER

This letter is to certify that, Vitalie Goreacii, employed by Sanmedico SRL located at: Republic of Moldova, city Chisinau, str. Petricani 88/1 of. 10, MD-2059, have received all required training and is enabled and authorized to provide services with installation, commissioning, and maintenance to the products listed below:

Mission® U120 Urine Analyzer
Mission® U120 Ultra Urine Analyzer
Mission® U500 Urine Analyzer
Mission® PT/INR Coagulation Monitoring System
Mission® Cholesterol Monitoring System
Mission® Ultra Cholesterol Monitoring System
Mission® HB Hemoglobin Testing System
Mission® Plus HB Hemoglobin Testing System
OnCall® Glucose Meter

For further questions or inquiries regarding this matter, please refer to the contact information below.

Sincerely

ACON LABORATORIES, INC. S.A.

Jassy Alvarenga
International Account Manager
ACON Laboratories, Inc.
jalvarenga@aconlabs.com
+1 858 875 8085

Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121 USA

We, the manufacturer, declare under our sole responsibility that the in vitro diagnostic device:

Device Name	REF Number
On Call® Plus Blood Glucose Monitoring System	G113-111
On Call® Plus Blood Glucose Meter	G113-211, G113-214
On Call® Plus Blood Glucose Test Strips	G133-111, G133-112, G133-114, G133-115, G133-117, G133-118, G133-119, G133-211
On Call® Plus Glucose Control Solution	G123-311

classified for *Annex II List B* of the directive 98/79/EC, meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The declaration according to Annex IV of the Directive is based on approval by the notified body TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 MÜNCHEN, Germany, notified under No. 0123 to the EC Commission

This declaration is valid until expiration of EC Certificate
No. V1 104507 0003 Rev. 06
Expiration Date: 2025-05-26

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 25 day of May, 2022
in San Diego, CA USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
ACON Laboratories, Inc.

5850 Oberlin Drive #340·San Diego, CA 92121, USA · Tel: (858) 875-8000 · Fax: (858) 875-8099
E-mail: info@aconlabs.com

Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121 USA

We, the manufacturer, declare under our sole responsibility that the medical device:

Mission® Lancets (C121-3041)
On Call® Lancets (G124-10A)
Insight® Lancets (C121-3045)
Swiss Point of Care Lancets (G124-90AA)

of class IIA according to Annex IX rule 6 of the directive 93/42/EEC,

meets all the provisions of the directive 93/42/EEC as amended by directive 2007/47/EC concerning medical devices which apply to it.

This declaration is according to Annex II of the Directive and thus is based on approval by the notified body
TÜV SÜD Product Service GmbH,
Ridlerstraße 65,
80339 MÜNCHEN, Germany,
notified under No. 0123 to the EC Commission.

This declaration is valid until expiration of EC Certificate
No. G1 104507 0002 Rev. 01
Expiration Date: 2023-09-06

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 17 day of August, 2021
in San Diego, CA USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
ACON Laboratories, Inc.

5850 Oberlin Drive #340·San Diego, CA 92121, USA · Tel: (858) 875-8000 · Fax: (858) 875-8099
E-mail: info@aconlabs.com

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 104507 0002 Rev. 01

Manufacturer: **ACON Laboratories, Inc.**
5850 Oberlin Drive, #340
San Diego CA 92121
USA

Product Category(ies): Lancets, Safety Lancets

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: SH1974310

Valid from: 2019-10-24
Valid until: 2023-09-06

Date, 2019-10-24

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 104507 0002 Rev. 01

Facility(ies):

ACON Laboratories, Inc.
5850 Oberlin Drive, #340, San Diego CA 92121, USA

ACON Laboratories, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

AZURE Institute, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Providing unique solutions to worldwide healthcare

September 29, 2024

To whom it may concern:

LETTER OF STATEMENT

We:

ACON Laboratories Inc.,
5850 Oberlin Drive,
#340, San Diego, CA92121 USA

Hereby declare that for products:

1. G113-111 On Call Plus Blood Glucose Monitoring System
2. G113-211/G113-214 On Call Plus Blood Glucose Meter

The test memories can only be deleted manually (as described in User Manual page 28), the replacement of batteries in machines can not affect stored memories or clear it.

This Statement Letter will be only used for the tender submission, sales and marketing in Moldova.

Sincerely,

ACON LABORATORIES, INC.

Ian Ni
Regional Sales Director (Diabetes Care)
ACON Laboratories Inc.,

On·Call® Plus

Blood Glucose Monitoring System

Specification

Feature	Specification
Technology	Biosensor/Electrochemical, Glucose oxidase (GOD)
Result Calibration	Plasma-equivalent
Test Time	10 seconds
Sample Size	0.5 µL
Sample Type	Fresh capillary whole blood
Hematocrit Range	25 - 60%
Glucose Test Range	20 - 600 mg/dL (1.1 - 33.3 mmol/L)
Memory Storage	300 results with date and time
Test Averaging	7, 14, 30-day averages
Data Transfer	USB
Control Solution	3 levels
Audio Feature	Optional beep for sample detection, error messages
Automatic Shutoff	2 minutes after last action
Battery	One (1) CR 2032 3.0V coin cell battery
Battery Life	1,000 measurements
Operating Conditions	41 - 113 °F (5 - 45°C) and 10 - 90% relative humidity
Strip Storage Temperature	2-35°C
Expiration Date	24 months (6 months after first opening)

Catalog

Product Name	Catalog No.	Contents
On Call® Plus Blood Glucose Monitoring System	G113-111 √ †	1 Meter, 10 Test Strips, 1 Control Solution 1, 1 Lancing Device, 1 Manual, 1 Carrying Case, 1 Quick Reference Guide, 1 Warranty Card, 10 Lancets, 1 Code Chip, 1 Clear Cap (for testing on forearm and palm)
On Call® Plus Blood Glucose Meter	G113-211 √ †	1 Meter, 1 Control Solution 1, 1 Carrying Case, 1 Manual, 1 Warranty Card, 1 Quick Reference Guide
	G113-214 √	1 Meter, 1 Lancing Device, 1 Control Solution 1, 1 Manual, 1 Carrying Case, 1 Quick Reference Guide, 10 Lancets, 1 Warranty Card, 1 Clear Cap (for testing on forearm and palm)
On Call® Plus Blood Glucose Test Strips	G133-111 √ †	50 Test Strips (25/vial), 1 Code Chip, 1 Package Insert
	50 Test Strips (50/vial), 1 Code Chip, 1 Package Insert
	G133-112 √	100 Test Strips (25/vial), 1 Code Chip, 1 Package Insert
	G133-114 √	10 Test Strips (10/vial), 1 Code Chip, 1 Package Insert
	G133-115 √	25 Test Strips (Individually Foil Wrapped), 1 Code Chip, 1 Package Insert
	G133-117 √	50 Test Strips (Individually Foil Wrapped), 1 Code Chip, 1 Package Insert
	G133-118 √	25 Test Strips (25/vial), 1 Code Chip, 1 Package Insert
On Call® Plus Blood Glucose Test Strips and Lancets	G133-211 √	50 Test Strips (25/vial), 50 Lancets (25/bag), 1 Code Chip, 1 Package Insert
On Call® Plus Blood Glucose Control Solution	G123-311 √†	1 Control Solution 0, 1 Control Solution 1, 1 Control Solution 2, 1 Package Insert
On Call® Lancets	G124-10A √†	100 Lancets (25/bag)
On Call® Lancing Device	G124-11A√	1 Lancing Device, 1 Package Insert
On Call® Diabetes Management Software Kit	G124-13A†	1 USB Data Transfer Cable, 1 Installation Disk

√ CE Marked for sale in the European Community CE 0123 † US 510(k) Cleared and CLIA Waived

ACON®

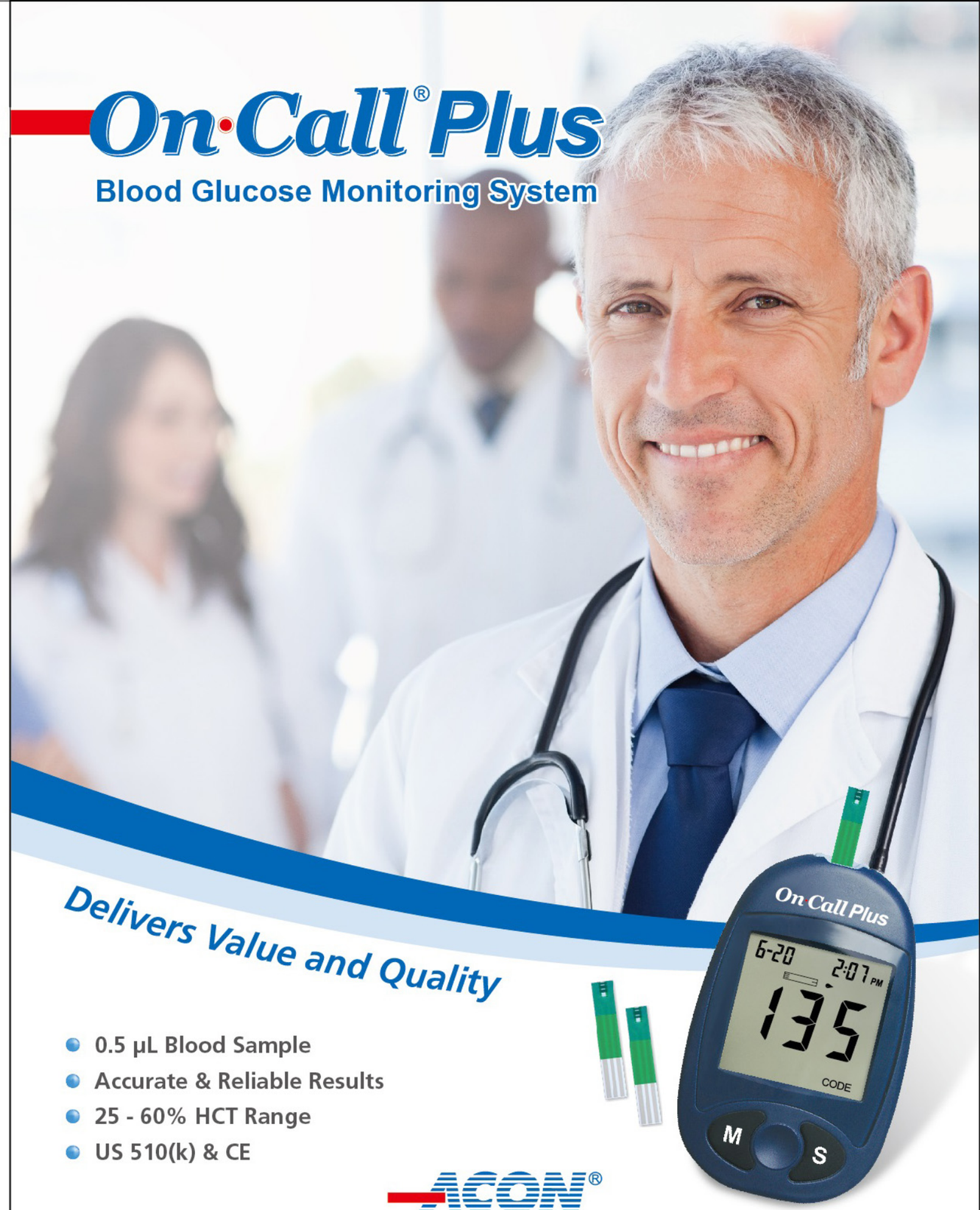
***ACON* Laboratories, Inc.**, 10125 Mesa Rim Road, San Diego, CA 92121, USA • Tel: 1-858-875-8000 • Fax: 1-858-200-0729 • E-mail: info@aconlabs.com

Please visit our website for details: www.acondiabetescare.com

1150944001

On·Call® Plus

Blood Glucose Monitoring System



Delivers Value and Quality

- 0.5 µL Blood Sample
- Accurate & Reliable Results
- 25 - 60% HCT Range
- US 510(k) & CE

ACON®

Diabetes Care

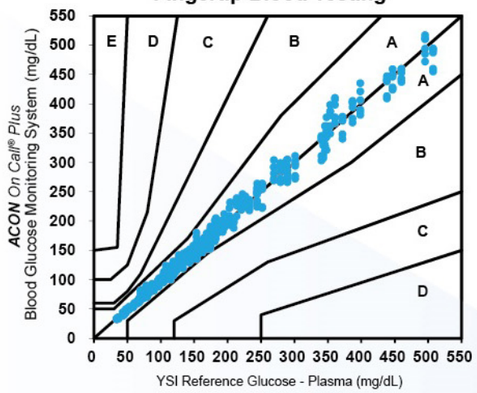
On·Call® Plus

Blood Glucose Monitoring System

Accurate and Reliable

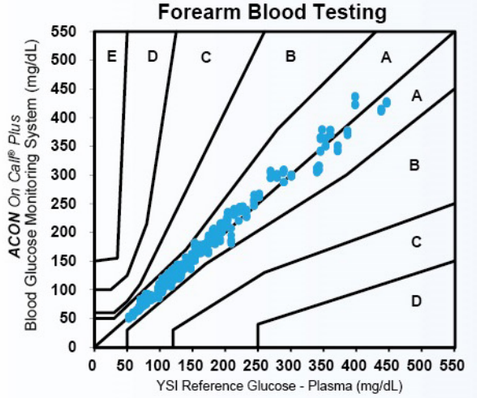
Extensive clinical studies proved the accuracy of *On Call® Plus* Blood Glucose Monitoring System with fresh capillary blood samples, which can comply with **EN ISO 15197: 2015**.

Fingertip Blood Testing



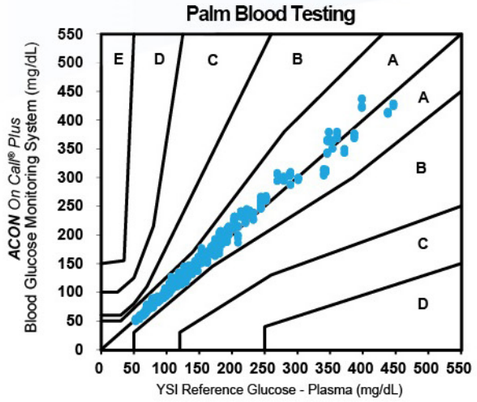
Consensus Error Grid Analysis Clinical Trial - Fingertip Capillary Blood, by Technican *ACON On Call® Plus* Blood Glucose Monitoring System vs. YSI		
System Accuracy Results for Glucose Concentration ≥ 100 mg/dL		
Within ±5%	Within ±10%	Within ±15%
290 / 462 (62.8%)	432 / 462 (93.5%)	462 / 462 (100.0%)
System Accuracy Results for Glucose Concentration <100 mg/dL		
Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
145 / 198 (73.2%)	193 / 198 (97.5%)	198 / 198 (100.0%)
System Accuracy Results for both Glucose Concentration ≥ 100 mg/dL and < 100 mg/dL		
Within ±15% or ±15 mg/dL		
658 / 660 (99.7%)		

Forearm Blood Testing



Consensus Error Grid Analysis Clinical Trial - Forearm Capillary Blood, by Technican *ACON On Call® Plus* Blood Glucose Monitoring System vs. YSI		
System Accuracy Results for Glucose Concentration ≥ 100 mg/dL		
Within ± 5%	Within ± 10%	Within ± 15%
202 / 444 (45.5%)	375 / 444 (84.5%)	440 / 444 (99.1%)
System Accuracy Results for Glucose Concentration <100 mg/dL		
Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
110 / 168 (65.5%)	154 / 168 (91.7%)	168 / 168 (100.0%)
System Accuracy Results for both Glucose Concentration ≥ 100 mg/dL and < 100 mg/dL		
Within ±15% or ±15 mg/dL		
608 / 612 (99.3%)		

Palm Blood Testing



Consensus Error Grid Analysis Clinical Trial - Palm Capillary Blood, by Technican *ACON On Call® Plus* Blood Glucose Monitoring System vs. YSI		
System Accuracy Results for Glucose Concentration ≥ 100 mg/dL		
Within ±5%	Within ±10%	Within ±15%
219 / 444 (49.3%)	395 / 444 (89.0%)	441 / 444 (99.3%)
System Accuracy Results for Glucose Concentration < 100 mg/dL		
Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
130 / 168 (77.4%)	166 / 168 (98.8%)	168 / 168 (100.0%)
System Accuracy Results for both Glucose Concentration ≥ 100 mg/dL and < 100 mg/dL		
Within ±15% or ±15 mg/dL		
609 / 612 (99.5%)		

On·Call® Plus

Blood Glucose Monitoring System

Key Features

- 0.5 µL blood sample
- HCT 25 - 60% HCT range
- 2 - 35°C strip storage temperature
- Optional individually packaged test strips available
- Alternative testing sites including fingertip, forearm and palm
- Automatic detection of insufficient sample
- 300 test memory with date and time
- 7, 14, 30 - day averages calculation
- Easy PC data transfer and smart App data analysis

Authority Certificate

CE certificate

USFDA CFG certificate

Health Canada certificate

Distributed by:

CLIAwaived.com™

11578 Sorrento Valley Road, Suite 25/26
San Diego, CA 92121
888-882-7739

Number: 1150591402
Effective date: 2010-11-11

On·Call® Plus

Blood Glucose Monitoring System

User's Manual

On·Call® Plus

Blood Glucose Monitoring System

Self monitoring of blood glucose (SMBG) is an integral part of diabetes care, but the high cost of testing can make this impossible. At *ACON*, our goal is to provide high quality glucose monitoring at a price that allows you to test as often as necessary. Together, we can better manage your diabetes and help you live a longer and healthier life.

Welcome, and thank you for choosing the *On Call® Plus* Blood Glucose Monitoring System. The *On Call® Plus* Blood Glucose Monitoring System will give you accurate blood glucose results in just a few simple steps.

To ensure accurate results from your *On Call® Plus* Blood Glucose Monitoring System, please follow these guidelines:

- Read instructions before use.
- Use the code chip that accompanies each box of test strips.
- Use only *On Call® Plus* Blood Glucose Test Strips with the *On Call® Plus* Blood Glucose Meter.
- For *in vitro* diagnostic use only. Your blood glucose monitoring system is to be used only outside the body for testing purposes.
- For self testing and professional use.
- Test only whole blood samples with the *On Call® Plus* Blood Glucose Test Strips and Meter.
- For self-testers, consult your physician or diabetes healthcare professional before making any adjustments to your medication, diet or activity routines.
- Keep out of reach of children.
- For help with any additional questions or issues, please contact Customer Support at 1-800-838-9502.

By following the instructions outlined in this User's Manual, you will be able to use your *On Call® Plus* Blood Glucose Monitoring System to monitor your blood glucose and better manage your diabetes.

Table of Contents

En

Getting Started

Before testing, read the instructions carefully and learn about all the components of your *On Call® Plus* Blood Glucose Monitoring System. Depending on the *On Call® Plus* product you purchase, some of the components may need to be purchased separately. Please check the list of contents on the outer box for details on which components are included with your purchase.

Blood Glucose Meter

Test Strips

Code Chip

Lancing Device

Clear Cap

Sterile Lancet

Control Solution

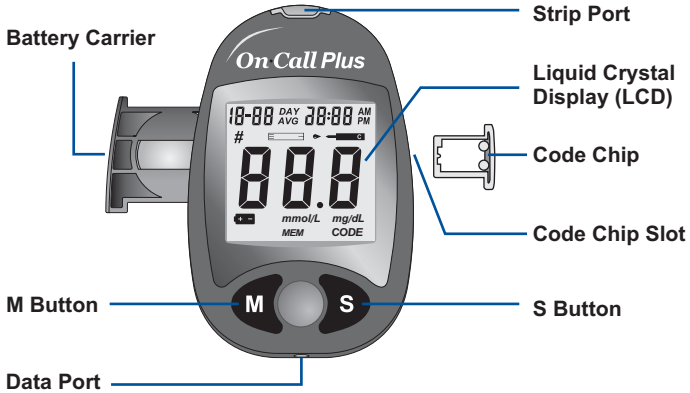
Carrying Case

Component Descriptions

1. Blood Glucose Meter: Reads the test strips and displays the blood glucose concentration.
2. Test Strips: Strips with a chemical reagent system used with the meter to measure glucose concentration in blood.
3. Code Chip: Automatically calibrates the meter with the code number when inserted into the meter.
4. Lancing Device: Used with sterile lancets to prick the fingertip, palm (at the base of the thumb) or forearm for blood sample collection. The packaged lancing device has multiple depth settings, allowing users to adjust the depth of the puncture and minimize discomfort.
5. Clear Cap: Used with the lancing device and sterile lancet to draw blood sample from the forearm and palm.
6. Sterile Lancets: Used with the lancing device to draw a blood sample. Sterile lancets are inserted into the lancing device with each blood draw and discarded after use.
7. Control Solution: Verifies the proper operation of the blood glucose monitoring system by checking the test strips and meter against a precalibrated control solution. Control Solution 1 is all you need most of the time. Control Solution 2 is also available if you want to do a level 2 test. The two levels of control solution, Control 1 and Control 2, are available in the *On Call® Plus* Glucose Control Solution package which is sold separately.
8. Carrying Case: Provides portability for blood glucose testing wherever you go.
9. User's Manual: Provides detailed instructions on using the blood glucose monitoring system.
10. Quick Reference Guide: Provides a brief overview of the blood glucose monitoring system and testing procedures. This small guide can be kept in your carrying case.
11. Quick Start Guide: A short set of instructions to get you started testing with your new system.
12. Logbook: Allows users to record their blood glucose data and get a better picture of their broader trends.
13. Warranty Card: Should be completed and returned to the warranty center to qualify for the 5-year meter warranty.

On Call® Plus Blood Glucose Meter

The meter reads the test strips and displays the blood glucose concentration. Use this diagram to become familiar with all the parts of your meter.



Liquid Crystal Display (LCD): Shows your test results, and helps you through the testing process.

M Button: Recalls previous test results from the meter memory and performs other menu selection functions.

S Button: Selects meter settings, performs other menu selection functions.

Strip Port: Test strips are inserted into this area to perform a test.

Battery Carrier: The battery carrier is located on the back of the meter.

Code Chip Slot: Insert the code chip here.

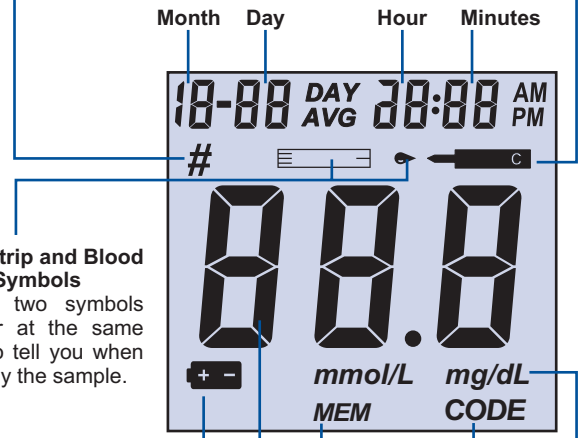
Code Chip: For coding the meter. A new code chip comes with every box of test strips.

Data Port: Not Currently Available for Use.

Meter Display

Pound Sign (#)
Appears with the control solution test result or when you mark an invalid result to prevent it from being included in the averages.

Control Solution Symbol
Indicates a control test result. A pound sign (#) will also be displayed when control solution symbol appears.



Test Strip and Blood Drop Symbols
These two symbols appear at the same time to tell you when to apply the sample.

Battery Symbol
Warns when you should replace the battery.

Test Result Area
Indicates code number and test result.

MEM
Shows a test result stored in memory.

CODE
Appears with the code number of the test strips.

Measurement Unit
Only one unit will be displayed on your meter and cannot be adjusted.

Meter Use and Precautions

- The meter is pre-set to display blood glucose concentration in either millimoles per liter (mmol/L) or milligrams per deciliter (mg/dL) depending on which unit of measure is standard in your country. This unit of measure cannot be adjusted. The meter will be set to mg/dL by default when sold in the United States.
- Do not get water or other liquids inside the meter.
- Keep the strip port area clean.
- Keep your meter dry and avoid exposing it to extremes in temperature or humidity. Do not leave it in your car.
- Do not drop the meter or get it wet. If you do drop the meter or get it wet, check the meter by running a quality control test. Refer to **Quality Control Test** on page 14 for instructions.
- Do not take the meter apart. Taking the meter apart will void the warranty.
- Refer to the **Caring for Your Meter** section on page 28 for details on cleaning the meter.
- Keep the meter and all associated parts out of reach of children.

Note: Follow proper precautions and all local regulations when disposing of the meter and used batteries.

On Call® Plus Blood Glucose Test Strips

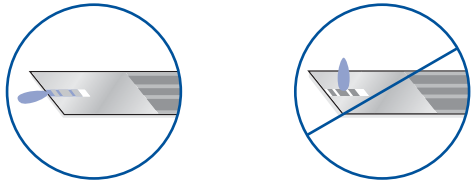
The *On Call® Plus* Blood Glucose Test Strips are thin strips with a chemical reagent which work with the *On Call® Plus* Blood Glucose Meter to measure the glucose concentration in whole blood. After the strip is inserted into the meter, blood is applied to the sample tip of the test strip, then automatically absorbed into the reaction cell where the reaction takes place. A transient electrical current is formed during the reaction and the blood glucose concentration is calculated based on the electrical current detected by the meter, then the result is shown on the meter display. The meter is calibrated to display plasma equivalent results.

Sample Tip
Apply blood or control solution here.

Check Window
Check to confirm that sufficient sample has been applied.

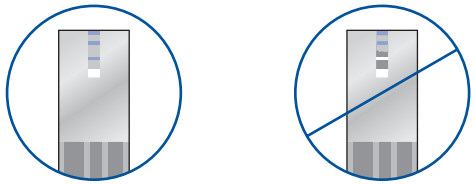
Contact Bars
Insert this end of the test strip into the meter until it stops.

IMPORTANT: Apply sample only to the sample tip of the test strip. Do not apply blood or control solution to the top of the test strip as this may result in an inaccurate reading.



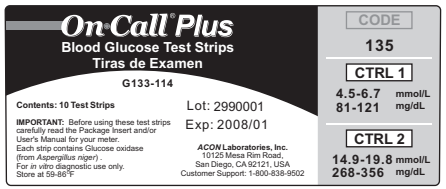
Correct **Incorrect**

Hold the blood drop to the sample tip of the test strip until the check window is full and until the meter begins to count down. If the check window does not fill, do not add more blood to the test strip. You may get an E-5 message or an inaccurate test result. Discard the strip and retest. Even if the meter begins to countdown but the check window does not fill, discard the strip and begin the test again with a fresh test strip.



Correct **Incorrect**

Code Number



Each package of test strips is printed with a code number (CODE), lot number (LOT), unopened expiration date (⌛) and control range (CTRL1 and CTRL 2).

Storage and Handling

Please review the following storage and handling instructions:

- Store test strips in a cool, dry place at room temperature, 59-86°F (15-30°C). Store them away from heat and direct sunlight.
- Do not freeze or refrigerate.
- Do not store or use test strips in a humid place such as a bathroom.
- Do not store the meter, the test strips or control solution near bleach or cleaners that contain bleach.
- Replace the cap on the test strip vial immediately after removing a test strip.
- The test strip should be used immediately after removing it from container.
- Do not use your test strips past the unopened expiration date printed on the label. Using test strips past the unopened expiration date may produce incorrect test results.
  Note: The expiration date is printed in Year-Month format. 2008-01 means January, 2008.

Special Instructions for Test Strip in the Vial

- Test strips should be stored tightly capped in their protective vial to keep them in good working condition.
- Do not store test strips outside their protective vial. Test strips must be stored in the original vial with the cap tightly closed.
- Do not transfer test strips to a new vial or any other container.
- Replace the cap on the test strip vial immediately after removing a test strip.
- A new vial of test strips may be used for 3 months after first being opened. The opened expiration date is 3 months after the date the vial was first opened. Write the opened expiration date on the vial label after opening. Discard the vial 3 months after you first open it, usage after this period may result in inaccurate readings.

Special Instructions for Test Strip in Foil Pouch

- Tear the pouch carefully starting from the tear gap. Avoid damaging or bending the test strip.
- Use test strip immediately after removing it from the pouch.

Test Strip Precautions

- For *in vitro* diagnostic use. Test strips are to be used only outside the body for testing purposes.
- Do not use test strips that are torn, bent, or damaged in any way. Do not reuse test strips.
- Before running a blood glucose test, make sure that the code number on the meter display matches the number shown on the test strip vial or on the pouch.
- Keep the test strip vial or the foil pouch away from children and animals.
- Consult your physician or healthcare professional before making any changes in your treatment plan based on your blood glucose test results.
- Not intended for the diagnosis of or screening for diabetes mellitus.
- Not for use on neonates.
- When testing alternative sites, test when in steady state only (such as before eating, before taking medication, before exercising, or 2 hours after eating).

See the test strip insert for more details.

On Call® Plus Glucose Control Solution

The *On Call® Plus* Glucose Control Solution contains a known concentration of glucose. It is used to confirm that your *On Call® Plus* Blood Glucose Meter and Test Strips are working together properly and that you are performing the test correctly. It is important to run a quality control test regularly to make sure you are getting correct results.

You should run a quality control test:

- Before you first use your meter, to familiarize yourself with its operation.
- Before using a new box of test strips.
- When you suspect that the meter or test strips are not working properly.
- When you suspect that your test results are inaccurate, or if they are inconsistent with how you feel.
- When you suspect your meter is damaged.
- After cleaning your meter.
- At least once a week.

Refer to **Quality Control Test** on page 14 for instructions on running a quality control test.

Please review the following storage and handling instructions:

Storage and Handling

- Store the control solution at room temperature, 59-86°F (15-30°C).
- Do not refrigerate or freeze.
- If the control solution is cold, do not use until it has warmed to room temperature.
- Use before the unopened expiration date that is shown on the bottle.
  Note: The expiration date is printed in Year-Month format. 2008-01 means January, 2008.
- Each bottle of control solution can be used for 3 months after you first open it. The control solution will expire 3 months after the bottle is opened for the first time. Record this opened expiration date on the bottle label.

Control Solution Precautions

- For *in vitro* diagnostic use. The control solution is for testing only outside the body. Do not swallow or inject.
- Shake well before using.
- Control solution tests are specified to be accurate only when tested between 59 and 104°F (15-40°C).
- The control ranges shown on the test strip vial (or on the foil pouch) are not recommended ranges for your blood glucose level. Your personal blood glucose target ranges should be determined by your diabetes healthcare professional.
- Do not touch the test strip with the tip of the control solution bottle.
- Use only the same brand of control solution that was provided with your kit.

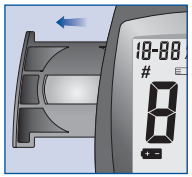
Please contact Customer Support at 1-800-838-9502 for more information on obtaining the control solution kit.

See the control solution insert for more details.

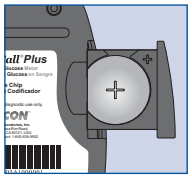
Install the Battery

Battery may not be preinstalled in the meter. One CR 2032 3.0V coin cell battery is required. Please find the battery in your carrying case and install it according to following steps:

1. Pull the battery carrier on the left side of the meter. The battery carrier should be easily opened with your finger.



2. Place a new CR 2032 3.0V coin cell battery. Make sure it is aligned with the (+) side facing up in the battery carrier.



3. Close the battery carrier and make sure that it snaps shut.

Meter Setup Before Testing

Before testing, the following steps should be followed:

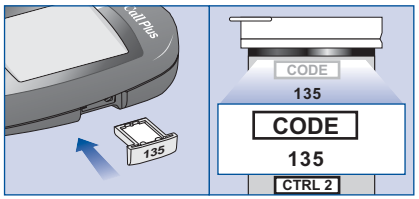
Step 1 - Coding the Meter

Simply insert the code chip to code the meter. Every time you change to a new box of test strips, you need to insert the code chip packed with the new box of test strips. You can see the code number appears on the meter. Make sure this number matches the code number printed on the test strip vial label (or on the foil pouch) and the number printed on the code chip.

You can easily find a code chip in your starter kit box. This code chip is used with the test strip packed in your carrying case when you first open the carrying case. If there is already one code chip inserted, remove it and insert the new code chip.

1. Take the code chip from the test strip box. Compare the code number on the code chip with the code number printed on the test strip vial label (or on the foil pouch). If the two numbers are not identical, you may get inaccurate results. If the code number on the code chip does not match the number on the vial or foil pouch of strips with which it was packaged, please contact Customer Support at 1-800-838-9502.

2. With your meter turned off, insert the new code chip into the code chip slot of the meter. It should easily snap into place. The code chip should remain in the meter, do not take it out until you change to another new box of test strips.

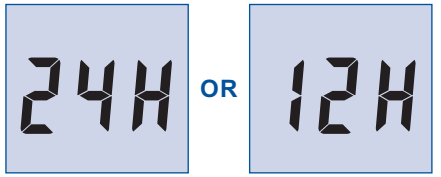


Note: If a test strip is inserted and no strip code is stored in memory, the display will flash "- - - CODE".

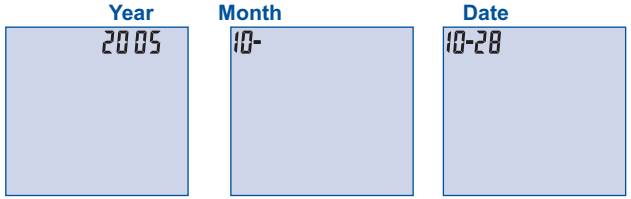
Step 2 - Adjusting the Meter Settings

Adjust the meter settings to set the clock, ensuring that results stored in the memory are shown with the correct date and time. You can also turn the meter audio feature on or off. You need to adjust the meter settings before you first use your meter.
You will need to set the clock settings after replacing the battery.

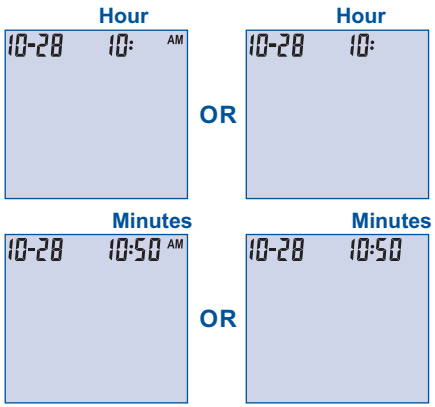
1. Press the S button to enter the meter setup mode. The meter will automatically enter the setup mode when turned on for the first time by any method.
2. First, set the clock for either 12 or 24 hour mode. Press the M button to switch between the two settings, then press the S button to save your choice and start setting the year, month and date.



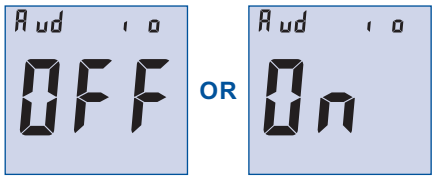
3. The year will appear at the top of the display. Press the M button until the correct year is displayed. Once you have selected the correct year, press the S button to save your choice and start setting the month. Press the M button until the correct month is displayed, then press the S button to save your choice and start setting the date. Press the M button until the correct date is displayed, then press the S button to save your choice and start setting the time.



4. The hour will appear at the top of the display. Adjust the hour with the M button until the correct hour is displayed. Press the S button to save your choice and set the minutes. Press the M button to change to the correct minute. Press the S button to save your choice and move to set the audio feature.



5. Audio Feature
   The meter comes with the meter audio feature enabled. The meter will give one short beep when it is turned on, after sufficient sample has been applied to the test strip and when the result is ready. The meter will sound three short beeps to sound a warning when an error has occurred. Please check the error number on the display to confirm what kind of error has occurred.
   Press the M button to switch between turning the meter beep "On" and "Off". Press the S button to confirm your selection. Pressing S at this point will end the setup mode and power off the meter.

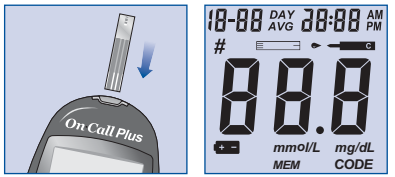


Performing a Quality Control Test

The quality control test confirms that the test strips and meter are working together properly, and that you are performing the test correctly. It is important to perform this test:

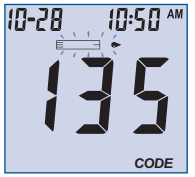
- Before you first use your meter.
- Before using a new box of test strips.
- When you suspect that the meter or test strips are not working properly.
- When you suspect that your test results are inaccurate, or if they are inconsistent with how you feel.
- When you suspect your meter is damaged.
- At least once a week.

1. Insert a test strip into the strip port, contact bars end first and facing up, to turn on the meter and display all the display segments. If the audio option is on, the meter will beep, signaling the meter is turned on.



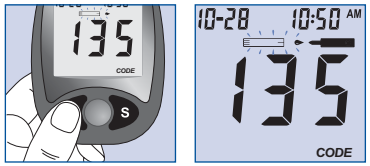
2. Check the display to confirm that all the display segments turn on (see display illustration above).

3. Following this display check, the system will enter the test mode. The display will show the date and time and the strip icon with the blood sample icon blinking. The code number will be displayed in the center of the screen. Make sure that the code number that appears on the display matches the code number (CODE) on the test strip vial (or on the foil pouch). If not, make sure to locate and insert the code chip that came with the box of strips. If the codes still do not match, do not perform a test. You will need a new package of test strips to perform a test.



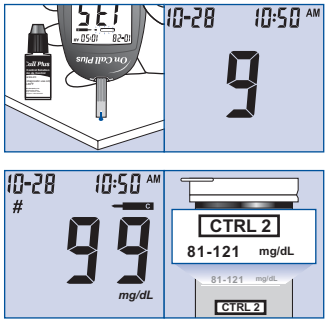
   The blinking test strip and blood drop icon indicates that the test strip is inserted correctly and a drop of control solution can be added.
   Note: If the test strip has been inserted incorrectly, the meter will not turn on.

4. Press the M button to mark the test as a control solution test. Once the M button is pressed, the control solution symbol will appear on the display.



5. Shake the control solution bottle well, then squeeze it gently and discard the first drop. If the tip clogs, tap the tip gently on a clean, hard surface, shake again, and then use. Squeeze out a second small drop on a clean nonabsorbent surface. Touch the sample tip of the test strip to the control solution drop. If the audio option is turned on, the meter will beep to indicate a sufficient sample has been applied.
   Notes:
   - Do not apply control solution to the test strip directly from the bottle.
   - If the control solution sample does not fill the check window, do not add a second drop. Discard the test strip and start over with a new test strip.

6. Once sufficient sample has been applied, the meter display will count down from 9 to 1 and then display the result. The control solution test results should be within the control range (CTRL1) printed on the test strip vial (or on the foil pouch). This means that your blood glucose monitoring system is working properly and that you are performing the procedure correctly.



Test results are displayed either in mmol/L or mg/dL depending on the unit of measure most common in your country. The meter will be set to mg/dL by default when sold in the United States.

7. Remove and discard the test strip.
   The display should also show a pound sign (#) indicating the test is a control solution test. This shows that the number will not be counted in the 7, 14 and 30-day averages. The pound sign (#) will also be displayed when reviewing the results stored in memory.
   If the result falls outside the indicated control range:
   - Confirm you are matching the correct range. Control Solution 1 results should be matched to the CTRL 1 range printed on the test strip vial (or on the foil pouch).
   - Check the expiration date of the test strip and control solution. Make sure that the test strip vial and control solution bottle have not been opened for more than 3 months. Discard any test strips or control solution that has expired.
   - Confirm the temperature in which you are testing is between 59 and 104℉ (15-40℃).
   - Make sure that the test strip vial and control solution bottle have been tightly capped.
   - Make sure code number on the strip vial label or on the foil pouch matches the code number appears on the meter display.
   - Confirm that you are using the same brand of control solution that was provided with your kit.
   - Make sure that you followed the test procedure correctly.

After checking all of the conditions listed above, repeat the quality control test with a new test strip. If your results still fall outside of the control range shown on the test strip vial (or on the foil pouch), your meter may be defective. Please contact Customer Support at 1-800-838-9502 for help.

Two levels of control solution are available labeled Control Solution 1 and Control Solution 2. Control Solution 1 is sufficient for most all self-testing needs. If you think your meter or strips may not be working correctly, you may also want to do a level 2 test. The ranges for both (CTRL 1 and CTRL 2) are displayed on the test strip vial (or on the foil pouch). Simply repeat step 4 through 6, using Control Solution 2.
For confirmation of results, Control Solution 1 tests should fall within the CTRL 1 range, and Control Solution 2 tests should fall within the CTRL 2 range. If the control solution test results do not fall within the respective ranges, DO NOT use the system to test blood, as the system may not be working properly. If you cannot fix the problem, please contact Customer Support at 1-800-838-9502 for help.
Please contact Customer Support at 1-800-838-9502 for more information on obtaining the *On Call® Plus* control solution kit, which contains Control Solution 1 and Control Solution 2.

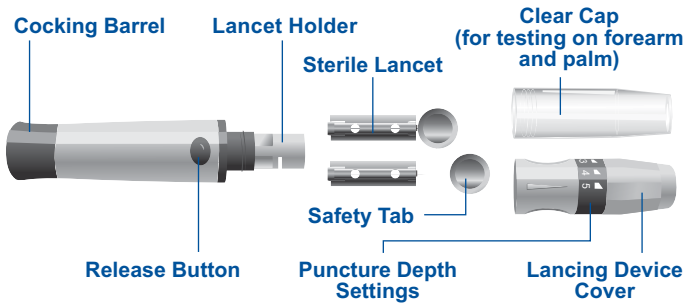
Testing Your Blood

The following steps show how to use the meter, test strips, lancing device and sterile lancets together to measure your blood glucose concentration.

Step 1 - Getting a Drop of Blood

The *On Call® Plus* Blood Glucose Monitoring System requires a very small sample of blood which may be obtained from the fingertip, palm (at the base of the thumb) or forearm. See page 20 for information on obtaining a blood sample from the palm or forearm. Before testing, choose a clean, dry work surface. Familiarize yourself with the procedure and make sure you have all the items needed to obtain a drop of blood.

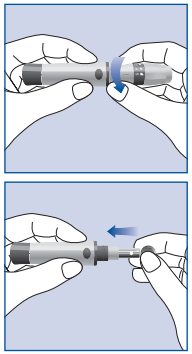
IMPORTANT: Prior to testing, wipe the test site with an alcohol swab or soapy water. Use warm water to increase blood flow if necessary. Then dry your hands and the test site thoroughly. Make sure there is no cream or lotion on the test site.



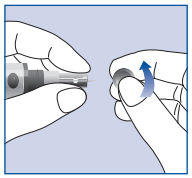
Fingertip Testing

For fingertip sampling, adjust the depth penetration to reduce the discomfort. You do not need the clear cap for fingertip sampling.

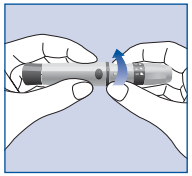
1. Unscrew the lancing device cover from the body of the lancing device. Insert a sterile lancet into the lancet holder and push it until the lancet comes to a complete stop in the lancet holder.



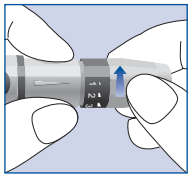
2. Hold the lancet firmly in the lancet holder and twist the safety tab of the lancet until it loosens, then pull the safety tab off the lancet. Save the safety tab for lancet disposal.



3. Carefully screw the cover back onto the lancing device. Avoid contact with the exposed needle. Make sure the cover is fully sealed on the lancing device.

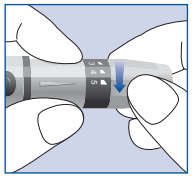


4. Adjust the puncture depth by rotating the lancing device cover. There are a total of 5 puncture depth settings. To reduce the discomfort, use the lowest setting that still

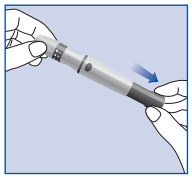


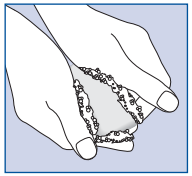
produces an adequate drop of blood.

Adjustment:
1 and 2 for delicate skin
3 for normal skin
4 and 5 for calloused or thick skin
Note: Greater pressure of the lancing device against the finger will also increase the puncture depth.

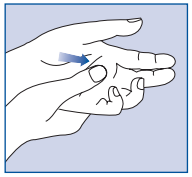


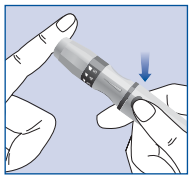
5. Pull the cocking barrel back to set the lancing device. You may hear a click. The device is now loaded and ready for obtaining a drop of blood.





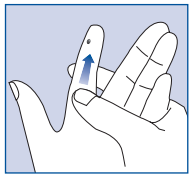
6. Prior to testing, wipe your hand with an alcohol swab or wash your hands with soap. Use warm water to increase blood flow in your fingers if necessary. Then dry your hands thoroughly. Massage the hand from the wrist up to the fingertip a few times to encourage blood flow.





7. Hold the lancing device against the side of the finger to be lanced with the cover resting on the finger. Push the release button to prick your fingertip. You should hear a click as the lancing device activates. Gently massage from the base of the finger to the tip of the finger to obtain the required blood volume. Avoid smearing the drop of blood.

For the greatest reduction in pain, lance on the sides of the fingertips. Rotation of sites is recommended. Repeated punctures in the same spot can make your fingers sore and callused.



Forearm or Palm (at the base of the thumb) Testing

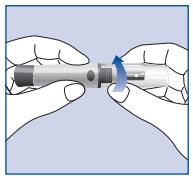
The forearm and palm areas have fewer nerve endings than the fingertip so you may find that obtaining blood from these sites is less painful than from the fingertip. The technique for forearm and palm sampling is different. You need the clear cap to draw blood from these sites. The clear cap is not adjustable for puncture depth.

IMPORTANT: There are important differences between forearm, palm and fingertip samples that you should know. Important information about forearm and palm glucose testing:

- You should talk to your healthcare professional before doing forearm or plam glucose testing.
- When blood levels are changing rapidly such as after a meal, insulin dose or exercise, blood from the fingertips may show these changes more rapidly than blood from other areas.
- Fingertips should be used if testing is within 2 hours of a meal, insulin dose or exercise and any time you feel glucose levels are changing rapidly.
- You should test with the fingertips anytime there is a concern for hypoglycemia or you suffer from hypoglycemia unawareness.

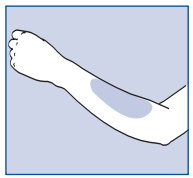
Please refer to **Fingertip Testing** to insert the lancet and load the lancing device.

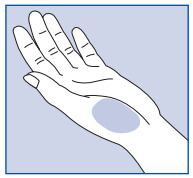
1. Screw the clear cap onto the lancing device.



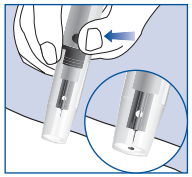
2. Choose a puncture site on the forearm or palm. Select a soft, fleshy area of the forearm that is clean and dry, away from bone, and free of visible veins and hair.

To bring fresh blood to the surface of the puncture site, massage the puncture site vigorously for a few seconds until you feel it getting warm.



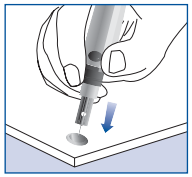


3. Place the lancing device against the puncture site. Press and hold the clear cap against the puncture site for a few seconds. Press the release button of the lancing device, but **do not immediately lift the lancing device** from the puncture site. Continue to hold the lancing device against the puncture site until you can confirm a sufficient blood sample has formed.

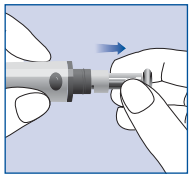


Disposal of the Lancet

1. Unscrew the lancing device cover. Place the safety tab of the lancet on a hard surface and carefully insert the lancet needle into the safety tab.



2. Press the release button to make sure that the lancet is in the extended position. Pull the lancet straight out of the lancet holder and discard it in an appropriate container. Place the lancing device cover back on the lancing device.



Lancet Precautions

- Do not use the lancet if the safety tab is missing or loose when you take the lancet out of the bag.
- Do not use the lancet if the needle is bent.
- Use caution whenever the lancet needle is exposed.
- Never share lancets or the lancing device with other people to prevent possible infections.
- In order to reduce the risk of infection from prior use of the instrument, always use a new, sterile lancet. Do not reuse lancets.
- Avoid getting the lancing device or lancets dirty with hand lotion, oils, dirt or debris.
- For AST testing, if current lancet is not obtaining enough blood due to skin or other conditions, please contact Customer Support at 1-800-838-9502 for information on different lancet options.

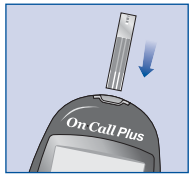
Specimen collection and preparation by healthcare professionals

Please refer to test strip insert if applicable.

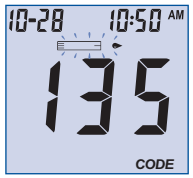
Step 2 - Testing Blood Glucose

Note: Insertion of a new test strip at any time, except while in the data transfer mode (detailed on page 28) will cause the meter to automatically enter the test mode.

1. Insert a test strip into the strip port, contact bars end first and facing up, to turn on the meter and display all the display segments. If the audio option is on, the meter will beep, signaling the meter is turned on.

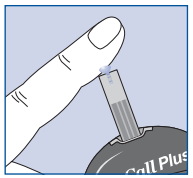


Make sure that the code number that appears on the display matches the code number (CODE) on the test strip vial (or on the foil pouch). If not, make sure to locate and insert the code chip that came with the box of strips. If the codes still do not match, do not perform a test. You will need a new package of test strips to perform a test.



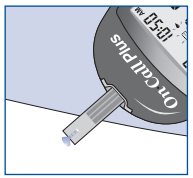
2. The blinking test strip and blood drop icon will indicate that the test strip is inserted correctly and a drop of blood can be added.

3. Touch the blood sample to the sample tip at the end of the test strip. If the audio option is turned on, the meter will also beep to indicate the sample is sufficient and the measurement has started.

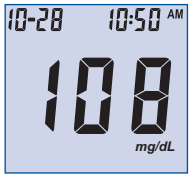


DO NOT:

- Apply sample to the front or back of the test strip.
- Smear the blood drop onto the test strip.
- Press your finger against the test strip.
- Apply a second drop of blood.



4. The meter will count down from 9 to 1 and then display the measurement results. The meter will also beep to indicate that measurement is complete.



   To mark invalid results and to prevent them from being included in the 7, 14 and 30 day averages, press the M and S buttons together. A pound sign (#) will appear on the display to show that the result will not be included when calculating the 7, 14 and 30-day averages. If a result is marked by accident, press the M and S buttons again to unmark the result. After marking the invalid result, run the test again with a new test strip.

   If an error message appears on the display, refer to the **Troubleshooting Guide** on page 31. If a "HI" or "LO" error appears on the display, refer to "HI" and "LO" messages below.

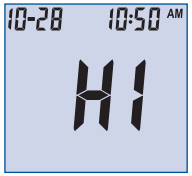
5. After inspection, record valid results in your logbook with the date and time, and compare them to the target goals set by your healthcare professional. Refer to **Suggested Testing Times and Target Goals** on page 29 and your logbook for more details on your target blood glucose concentration goals.

6. Remove and discard the test strip.

"HI" and "LO" Messages

The meter can accurately measure blood glucose concentrations between 1.1 to 33.3 mmol/L (20 to 600 mg/dL). "HI" and "LO" messages indicate results outside of this range.

If "HI" appears on the display, the measured concentration value is above 33.3 mmol/L (600 mg/dL). The test should be retaken to ensure that no mistake was made in the procedure. If you are certain the meter is functioning properly and no mistakes were made in the procedure, and your blood glucose is still consistently measured as "HI", it indicates severe hyperglycemia (high blood glucose). You should contact your healthcare professional immediately.



If "LO" appears on the display, the measured concentration value is below 1.1 mmol/L (20 mg/dL). The test should be retaken to ensure that no mistake was made in the procedure. If you are certain the meter is functioning properly and no mistakes were made in the procedure, and your blood glucose is still consistently measured as "LO", it may indicate severe hypoglycemia (low blood glucose). You should treat yourself for hypoglycemia immediately as recommended by your healthcare professional.

Precautions and Limitations

- The meter, test strips and other components have been designed, tested and proven to work together effectively to provide accurate blood glucose measurements. Do not use components from other brands.
- Use only with whole blood. Do not use with serum or plasma samples.
- Do not use for testing newborns.
- Do not use the meter in any manner not specified by the manufacturer. Otherwise, the protection provided by the meter may be impaired.
- Very high (above 55%) and very low (below 30%) hematocrit can cause false results. Talk to your healthcare professional to find out your hematocrit level.

- Abnormally high levels of Vitamin C (ascorbic acid), Acetaminophen, Uric Acid, L-Dopa, Tolazamide or other reducing substances will produce falsely high blood glucose measurements.
- Fatty substances (Triglycerides up to 3,000 mg/dL or Cholesterol up to 500 mg/dL) have no major effect on blood glucose test results.
- The *On Call® Plus* Blood Glucose Monitoring System has been tested and shown to work properly up to 8,516 ft (2,595 meters).
- Severely ill persons should not run the glucose test with the *On Call® Plus* Blood Glucose Monitoring System.
- Blood samples from patients in shock, or with severe dehydration or from patients in a hyperosmolar state (with or without ketosis) have not been tested and are not recommended for testing with *On Call® Plus* Blood Glucose Monitoring System.
- Dispose of blood samples and materials carefully. Treat all blood samples as if they are infectious materials. Follow proper precautions when disposing of materials.

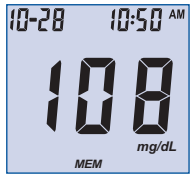
Using the Meter Memory

The meter automatically stores up to 300 test records. Each record includes the test result, time and date. If there are already 300 records in memory, the oldest record will be erased to make room for a new one. The meter will also calculate the average values of records from the last 7, 14 and 30 days.

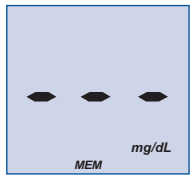
Viewing Stored Records

To view stored records:

1. Press the M button to turn the meter on and enter memory mode. The most recent value and the word "MEM" will appear on the display.



   If you are using the meter for the very first time, the meter display will show three dashed lines (---), the word "MEM" and the unit of measure. This shows that no data have been stored in memory.

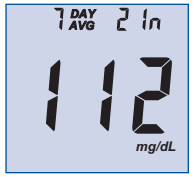


2. The date and time will be displayed together with the results stored in memory. A pound sign (#) indicates records that will be omitted from the 7, 14 and 30 day averages.

3. Press the M button to go through the stored records.

4. Press the S button to view the data averages. The words "DAY AVG" will appear on the screen.
   Note: If you do not wish to view your average glucose measurements, you can press the S button again to turn off the display.

5. While in memory mode, press the M button to switch between the 7, 14 and 30 day averages. The meter will calculate the average that you selected. The number of records used in the DAY AVG will also appear in the display.



6. If there are fewer than 7, 14 or 30 days in memory, all the unmarked readings currently stored in memory will be averaged instead.

   If you are using the meter for the very first time, no value will appear on the display. This means that no records have been stored in memory.

7. Press the S button to turn off the display.
   Note: Results from quality control tests will not be included in the averages. When viewing results in memory, these values are marked with a pound sign (#) to show that they will not be included in the 7, 14 and 30 day averages.

Clearing the Memory

Extreme caution should be used when clearing the memory. This is not a reversible operation. To clear the memory:

1. With the meter powered off, press and hold the M button for three seconds. This will turn on the meter and enter the delete mode.

2. To clear the memory, press and hold both the M and S buttons for two seconds.

3. The display will show "MEM" and "---", the meter will clear its memory and after a moment turn itself off.

4. If you entered the delete mode but want to exit without deleting the recorded data, press the S button. This will turn the meter off without deleting any data.

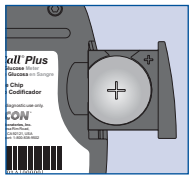
Maintenance

Proper maintenance is recommended for best results.

Replacing the Battery

When the battery icon (+ -) appears, it means the battery is running low and you should replace the battery as soon as possible. An "E-6" error message will appear if the battery is too low to perform any more blood glucose tests. The meter will not function until the battery is replaced.
Instructions:

1. Make sure the meter is off before removing the battery.
2. Pull the battery carrier on the left side of the meter. The battery carrier should be easily opened with you finger.
3. Remove and discard the old battery. Replace it with a new CR 2032 3.0V coin cell battery. Make sure it is aligned with the (+) side facing up in the battery carrier.
4. Close the battery carrier and make sure that it snaps shut.
5. Recheck and reset the clock setting as necessary after battery replacement to ensure time is set correctly. To set the meter clock, see **Meter Setup Before Testing** on page 11.



Caring for Your *On Call® Plus* Blood Glucose Monitoring System

Blood Glucose Meter

Your *On Call® Plus* Blood Glucose Meter does not require special maintenance or cleaning. A cloth dampened with water and a mild detergent solution can be used to wipe the outside of the meter. Take care to avoid getting liquids, dirt, blood or control solution into the meter through the strip or data ports. It is recommended that you store the meter in the carrying case after each use.
The *On Call® Plus* Blood Glucose Meter is a precision electronic instrument. Please handle it with care.

Lancing Device

Use mild soap and warm water to clean with a soft cloth as required. Carefully dry the device thoroughly. Do not immerse the lancing device. Please refer to the lancing device insert for more details.

Suggested Testing Times and Target Goals

Tracking your blood glucose concentration through frequent testing is an important part of proper diabetes care. Your diabetes health care professional will help you to decide the normal target range for your glucose levels. They will also help you determine when and how often to test your blood glucose. Some suggested times are:

- When you wake up (fasting level)
- Before breakfast
- 1-2 hours after breakfast
- Before lunch
- 1-2 hours after lunch
- Before or after exercise
- Before dinner
- 1-2 hours after dinner
- Before bedtime
- After a snack
- At 2 or 3 AM, if taking insulin

You may need to test more often whenever[1]:

- You add or adjust your medication for diabetes.
- You think your blood glucose levels may be too low or too high.
- You are ill, or feeling uncomfortable over long periods of time.

Expected blood glucose levels for people without diabetes:[2]

Time	Range, mg/dL	Range, mmol/L
Fasting and Before Meals	70 - 100	3.9 - 5.6
2 Hours after Meals	Less than 140	Less than 7.8

Talk to your diabetes healthcare professional to set your own daily target ranges.

Time of Day	Your Target Range
Waking up (Fasting level)	
Before meals	
2 hours after meals	
Bedtime	
2 AM to 3 AM	
Other	

(Note: 1 mmol/L = 18 mg/dL)

Use the logbook to record your blood glucose measurements and related information. Bring the logbook with you when visiting your physician so that you can determine how well your blood glucose is being controlled. This can help you and your health care professional make the best decisions about your glucose control plan.

1. Jennifer Mayfield and Stephen Havas, "Self-Control: A Physician's Guide to Blood Glucose Monitoring in the Management of Diabetes An American Family Physician Monograph"
2. ADA Clinical Practice Recommendations, 2010.

Comparing Meter and Laboratory Results

Your *On Call® Plus* Blood Glucose Monitoring System and laboratory results both report the glucose concentration in the serum or plasma component of your blood. However, the results may differ somewhat due to normal variation. This is expected, but the difference under normal operating conditions should be no greater than 20%.

Users should make accurate comparisons periodically between meters and laboratory results. Follow the guidelines below.

Before you go to the lab:

- Bring your meter, test strip and control solution with you to the lab.
- Make sure your meter is clean.
- Perform a quality control test to make sure the meter is working properly.
- Comparisons will be more accurate if you do not eat for at least four hours (preferably eight hours) before testing.

At the lab:

- Wash your hands before obtaining a blood sample.
- Obtain blood samples for a laboratory test and for your meter within 10 minutes of each other. This will ensure an accurate comparison of results.
- Never use your meter with blood that has been placed in test tubes containing fluoride or other anticoagulants. This will cause falsely low results.

Troubleshooting Guide

The meter has built-in messages to alert you of problems. When error messages appear, note the error number, turn off the meter and then follow these instructions.

Display	Causes	Solution
Meter fails to turn on	Battery may be damaged or not be charged	Replace battery.
	Meter is too cold	If meter has been exposed to or stored in cold conditions, wait 30 minutes to allow meter to reach room temperature then repeat test.
E-0	Power On self check error	Remove battery for 30 seconds and then put battery back and turn meter on again. If problem persists, contact customer support.
E-1	Internal calibration check error	If a cell phone, radio frequency source or a high power electrical source is nearby, place more distance between the meter and any of these sources then retest. If the problem persists, contact customer support.
E-2	Test strip was removed during the test	Repeat the test and ensure test strip remains in place.
E-3	Sample was applied to the test strip too soon	Repeat test and apply sample after blood drop/test strip icon appears.
E-4	Test strip is contaminated or used	Repeat test with a new test strip.
E-5	Insufficient sample	Repeat test and apply enough sample to fill the test strip check window.
HI t	Temperature has exceeded the operating temperature of the system	Move to a cooler environment and repeat the test.

Display	Causes	Solution
LO t	Temperature is below the operating temperature of the system	Move to a warmer environment and repeat the test.
	Battery is discharged but has enough power to run 10 more tests	Test results will still be accurate, but replace the battery as soon as possible.
E-6	Battery has discharged and meter does not allow more tests until replacement with a new battery	Replace the battery and repeat the test.
CODE	No code chip in the meter	Insert the code chip that accompanied the box of test strips.
E-7	Damaged code chip or the code chip was removed during a test	If the code chip is damaged, use a new code chip with the correct code number and run the test. If the chip is removed during a test, confirm the code chip matches the test strip code and repeat the test.
E-8	Meter electronics failure	If the problem persists, contact customer support.
E-9	Incorrect code chip inserted in the meter	Indicates an incorrect code chip was inserted in the meter. Please make sure you use the *On Call® Plus* brand of test strips with the *On Call® Plus* Blood Glucose Meter. If the problem persists, contact customer support.
E 10	Communications failure	There is an error in transferring data to the PC. See the package insert included with the Data Management Kit for troubleshooting.

For help with any additional questions or issues, please contact Customer Support at 1-800-838-9502.

Specifications

Feature	Specification
Measurement Range	20 to 600 mg/dL
Result Calibration	Plasma-equivalent
Sample	Fresh capillary whole blood
Minimum Sample Size	1 µL
Test Time	10 seconds
Power Source	One (1) CR 2032 3.0V coin cell battery
Battery Life	12 months or approximately 1,000 tests
Glucose Units of Measure	The meter is pre-set to either millimoles per liter (mmol/L) or milligrams per deciliter (mg/dL) depending on the standard of your country. The meter will be set to mg/dL by default when sold in the United States.
Memory	Up to 300 records with time and date
Meter Size	85mm x 54mm x 20.5mm
Display Size	35mm x 32.5mm
Weight	Approximately 49.5 g (with battery installed)
Operating Temperature	41 - 113°F(5-45°C)
Operating Relative Humidity	20-90% (non-condensing)
Hematocrit Range	30-55%

Warranty

Please complete the warranty card that came with this product and mail it to the following address:

On Call® Plus Warranty Center
10125 Mesa Rim Road,
San Diego, CA 92121-2915, USA

If the meter fails to work for any reason other than obvious abuse within the first five (5) years from purchase, we will replace it with a new meter free of charge. For your records, also write the purchase date of your product here.
Date of purchase: _____

Note: This warranty applies only to the meter in the original purchase, and does not apply to the battery supplied with the meter.

En

Index

Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121 USA

We, the manufacturer, declare under our sole responsibility that the medical device:

Mission® Lancets (C121-3041)
On Call® Lancets (G124-10A)
Insight® Lancets (C121-3045)
Swiss Point of Care Lancets (G124-90AA)

of class IIA according to Annex IX rule 6 of the directive 93/42/EEC,

meets all the provisions of the directive 93/42/EEC as amended by directive 2007/47/EC concerning medical devices which apply to it.

This declaration is according to Annex II of the Directive and thus is based on approval by the notified body
TÜV SÜD Product Service GmbH,
Ridlerstraße 65,
80339 MÜNCHEN, Germany,
notified under No. 0123 to the EC Commission.

This declaration is valid until expiration of EC Certificate
No. G1 104507 0002 Rev. 01
Expiration Date: 2023-09-06

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 17 day of August, 2021
in San Diego, CA USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
ACON Laboratories, Inc.

5850 Oberlin Drive #340·San Diego, CA 92121, USA · Tel: (858) 875-8000 · Fax: (858) 875-8099
E-mail: info@aconlabs.com

Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Mission® Hb Hemoglobin Testing System (C111-3021, C111-3031)

Mission® Hb Hemoglobin Test Strips (C131-3011, C131-3021)

Mission® Hb Hemoglobin Control Solution (C121-3091)

Mission® Hb Hemoglobin Control Strip (C121-3031)

Mission® Hb Data Transfer Kit (C121-3021)

classified as Others in the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 30 day of September, 2020
in San Diego, CA USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
Acon Laboratories, Inc.

Mission®

Hb Hemoglobin
Testing System

Accurately measures Hb and calculates Hct levels

Fast Results | **Portable** | **Accurate** | **Small Sample** | **Sample Type:** Capillary and Venous blood

ACON®

Quick

- Hemoglobin (Hb) and Hematocrit (Hct) results in < 15 seconds
- Simply insert strip, apply specimen and read results
- Low maintenance and quick clean up

Accurate

- Precise results equivalent to automatic hematology analyzers
- Wide Hb measurement range of 4.0-25.6 g/dL with Hct range of 13-75%
- Excellent precision in both low and high Hb concentration

Convenient

- Only 10 µL capillary or venous blood required
- Minimal training required, no specimen preparation
- Easy-to-read, large LCD screen
- Quick data transfer via Mini USB port

Specifications

FEATURE	TECHNICAL SPECIFICATION
Methodology	Reflectance Photometry
Detection Principle	Methemoglobin
Time to Results	< 15 seconds
Memory	1,000 tests with date/time and ID number
Specimen Volume	10 µL
Specimen Type	Capillary and Venous whole blood
Hb Measurement Range	4.0-25.6 g/dL (2.48-15.9 mmol/L)
Hct Range	13-75%
Wavelengths	525 nm
PC Interface	Mini USB Port
Calibration	Automatic
Hb Precision	4.0-10.0 g/dL: SD≤0.4g/dL 10.0-25.6 g/dL: CV≤3.0%
Accuracy	Venous Blood: Y=0.9582X+0.5673, R^2=0.9847; Capillary Blood: Y=1.0006X+0.026, R^2=0.9853.
Operating Conditions	10-40°C (50-104°F); ≤ 90% RH
Meter Storage Conditions	0-50°C (32-122°F); ≤ 90% RH
Strip Storage Conditions	2-30°C (36-86°F); ≤ 85% RH
Strip Shelf Life	2 years unopened canister; 3 months opened canister
Control Solution Shelf Life	6 months unopened bottle; 30 days opened bottle
Power Source	3 AAA Batteries or AC Adaptor
Battery Life	2,700 tests or 360 hours
Automatic Shut Off	8 minutes
Meter Dimensions (L X W X H)	127 mm × 58 mm × 25 mm (5.0" x 2.28" x 0.09")
LCD Dimensions (L X W)	39 mm × 37 mm (1.54" x 1.46")

Mission®

Hb Hemoglobin Meter

Ordering Information

PRODUCT NAME	CATALOG NO.	COMPONENTS			
Mission® Hb Hemoglobin Testing System	C111-3021√	1 Meter 10 Lancets (26G) 3 AAA Batteries 1 Users Manual	1 Warranty Card 10 Test Strips 1 Lancing Device 1 Carrying Case	1 Quick Reference Guide 1 Lancing Device Insert 1 Test Strip Insert 1 Code Chip	2 Control Strips 1 Control Strip Insert 10 Capillary Transfer Tubes 1 Tube Insert
	C111-3031√	1 Meter 2 Control Strips	3 AAA Batteries 1 Carrying Case	1 Manual 1 Quick Reference Guide	1 Control Strip Insert 1 Warranty Card
Mission® Hb Hemoglobin Test Strips	C131-3011√	25 Test Strips		1 Code Chip	1 Test Strip Insert
		50 Test Strips (25/Canister)		1 Code Chip	1 Test Strip Insert
		100 Test Strips (25/Canister)		1 Code Chip	1 Test Strip Insert
	C131-3021√	50 Test Strips (25/Canister) 50 Capillary Transfer Tubes - Glass/10 µL (25/Canister)		1 Code Chip	1 Test Strip Insert
Mission® Hb Hemoglobin Control Strips	C121-3031√	2 Control Strips (2/Canister)		1 Control Strip Insert	
Mission® Hb Hemoglobin Control Solution	C121-3091√	2 Bottles of Level-0 Control Solution (1 mL/bottle)			1 Control Solution Insert
		2 Bottles of Level-1 Control Solution (1 mL/bottle)			
		2 Bottles of Level-2 Control Solution (1 mL/bottle)			
Mission® Capillary Transfer Tubes	C121-3081	50 Capillary Transfer Tubes - Glass-tipped/10 µL			
Mission® Lancets	C121-3041*	100 Lancets (26G)		1 Package Insert	
Mission® Lancing Device	C121-3051√	1 Lancing Device		1 Lancing Device Insert	
Mission® Safety Lancets I	C121-3061*	25 Safety Lancets (21G/2.8 mm)			
Mission® Safety Lancets III	C121-3101	50 Safety Lancets (21G/2.2 mm)			
Mission® Adaptor Kit	C121-3011√	1 Power Adaptor		1 Plug	

√ CE Marked *CE 0123

www.aconlabs.com

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ACON®

ACON Laboratories, Inc.
5850 Oberlin Drive, #340
San Diego, CA 92121, USA

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

Number: 1151085101
Effective date: 2019-11-07

Mission®

Hb Hemoglobin Testing System

User's Manual

IVD

CE

Attention: By approving the enclosed design draft, you (ACON's Customer) accept all responsibility for the accuracy of the design. If an error is detected following the printing or manufacturing of a material, you (ACON's Customer) are responsible for the cost of any inventory which is deemed unsuitable for sale and/or not compliant with local regulations .

☐ US ■ OUS ☐ DOMESTIC ☐ OTHER

Description	Mission CE Hb User Manual-En-N		Part Number	1151085101	Size 110x165mm
Printing Contents			L Number		Size
Designer	rene	Design Date/Version	Aug 27, 2019/A		
Artwork checked by		Material	封面200g双铜纸+水性上光，内页80g双胶纸		Checked by
Approved by Customer		Approved by Marketing/Sales			
Approved by P.M.T.		Approved by QA			Effective Date

Table of Contents

Section 1 Introduction

The *Mission*® Hb Hemoglobin Testing System is intended for the quantitative determination of hemoglobin (Hb) and calculated hematocrit (Hct) in capillary and venous human whole blood. The easy to operate system consists of a portable meter that analyzes the intensity and color of light reflected from the reagent area of a test strip, ensuring quick and accurate results.

The *Mission*® Hb Hemoglobin Testing System provides results in less than 15 seconds and requires only a single drop of whole blood. The meter can store up to 1,000 results and records can be transferred to a computer for further analysis using the USB port. The meter can be operated by 3 AAA (1.5V) batteries or an optional AC adapter.

To ensure accurate results:

- Read instructions and complete any necessary training before use.
- Use the code chip that accompanies each box of test strips.
- Use only *Mission*® Hb Hemoglobin Test Strips with the *Mission*® Hb Hemoglobin Meter.
- For *in vitro* diagnostic use only.
- For professional use only.
- Test only whole blood specimens. EDTA or heparin anticoagulants can be used.
- Keep out of reach of children.

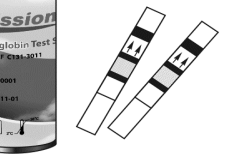
Note: Throughout this user guide, meter parts or functions will appear in **bold**. Items appearing on displays are identified in ***bold italics***.

Section 2 Getting Started

Inspect the kit box, meter and accessories for any visible damage. For US customers, call customer service toll free at 1-(800)-838-9502 if any visible damage exists. For customers outside the US, contact your local distributor. Remove the meter and other packaging contents from the kit box. The starter kit consists of the following:

Hb Meter

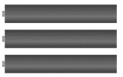
Canister of Test Strips



Code Chip

Control Strip

Capillary Transfer Tube/Dropper



AAA Batteries

Carrying Case

Lancing Device

Sterile Lancets

For REF C111-3021:

No.	Component	Quantity
1	Meter	1
2	Canister of Test Strips	1
3	Code Chip	1
4	Lancing Device	1
5	Sterile Lancets	10
6	Control Strips	2
7	Capillary Transfer Tubes/Droppers	10
8	AAA Batteries	3
9	Carrying Case	1
10	User's Manual	1
11	Quick Reference Guide	1
12	Test Strip Package Insert	1
13	Control Strip Package Insert	1
14	Lancing Device Package Insert	1
15	Warranty Card	1

Hb Meter: Reads the test strips and displays the hemoglobin (Hb) concentration and calculated hematocrit (Hct) value.

Test Strips: Part of the system and used with the meter to measure Hb concentration and calculated Hct in blood.

Code Chip: Automatically calibrates the meter with the code number when inserted into the meter.

Lancing Device: Used with sterile lancets to prick the fingertip for blood specimen collection. The packaged lancing device has multiple depth settings, allowing users to adjust the depth of the puncture and minimize discomfort. It can also eject the used lancets.

Sterile Lancets: Used with lancing device to draw blood specimens. Sterile lancets are inserted into the lancing device with each blood draw and discarded after use.

Control Strip: Verifies the proper operation of the meter by checking that the meter can detect a pre-calibrated value.

Capillary Transfer Tubes/Droppers: Collects 10 μL of capillary blood for fingertip blood testing and accurate results.

AAA Batteries：Provides power for the meter.

Carrying Case: Provides portability for testing.

User's Manual: Provides detailed instructions on using the Hb Hemoglobin Testing System.

Quick Reference Guide: Provides a brief overview of the Hb Hemoglobin Testing System and testing procedures.

Test Strip Package Insert: Provides detailed instructions on using the Hb Hemoglobin Test Strips.

Control Strip Package Insert: Provides detailed instructions on using the Hb Hemoglobin Control Strips.

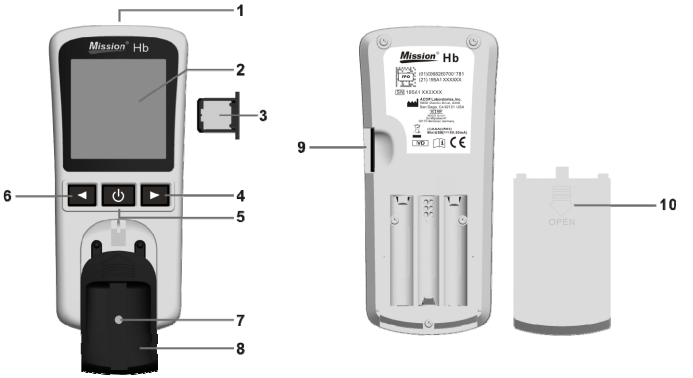
Lancing Device Package Insert: Provides detailed instructions on using the Lancing Device.

Warranty Card: Should be completed and returned to the distributor to qualify for the 2-year meter warranty.

Section 3 Components

The *Mission*® Hb Hemoglobin Meter reads the test strips and displays the hemoglobin (Hb) concentration and hematocrit (Hct) value. Use this diagram to become familiar with all the parts of your meter.

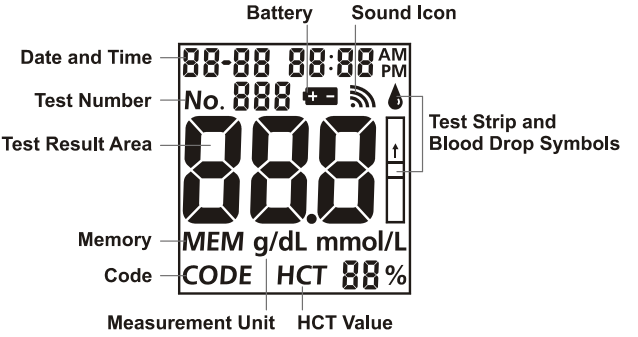
Meter



1	USB Port	**6**	Left Arrow ◄ Button
2	Liquid Crystal Display (LCD)	**7**	Strip Channel
3	Code Chip	**8**	Test Strip Holder
4	Right Arrow ► Button	**9**	Code Chip Slot
5	On/Off ⏻ Button	**10**	Battery Cover

Meter Display

During testing, the *Mission*® Hb Hemoglobin Meter will display icons showing the status, options available and prompts for testing:



Sound Icon: Appears when the sound is turned on.

Battery: Appears when the battery should be replaced.

Test Number: Indicates assigned test number.

Test Result Area: Indicates test result or displays menu options.

Memory: Indicates a test result is being recalled from memory.

Code: Indicates the code number of the test strips.

Measurement Units: Indicates the units for the test result.

HCT Value: Shows calculated Hct value.

Test Strip and Blood Drop Symbols: Indicates when to insert test strip or apply specimen.

Meter Use and Precautions

- Do not get water or other liquids inside the meter.
- Keep the Strip Channel clean.
- Keep the meter dry and avoid exposing it to extreme temperatures or humidity.
- Do not drop the meter or get it wet. If meter is dropped or has gotten wet, ensure the meter is working properly by running an Optical Check. Refer to Optical System Check in Section 8 for details.
- Do not take the meter apart. Taking the meter apart will void the warranty.
- Refer to Section 10 Maintenance for details on cleaning the meter.
- Keep the meter and all associated parts out of reach of children.

Note: Follow proper precautions and all local regulations when disposing of the meter and used batteries.

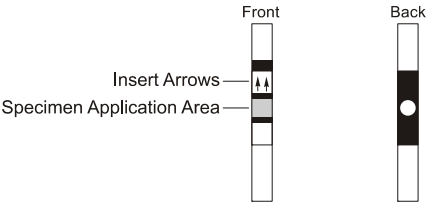
All Hb systems preventive warnings with regard to EMC

1. This instrument is tested for immunity to electrostatic discharge as specified in IEC 61000-4-2. However, use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets, etc.) may cause damaging static discharges that may cause erroneous results.
2. This instrument complies with the emission and immunity requirements described in EN 61326-1 and EN 61326-2-6. Do not use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with proper operation of the meter.
3. For professional use, the electromagnetic environment should be evaluated prior to operation of this device.

Test Strips

The *Mission*® Hb Hemoglobin Test Strips are thin plastic strips which contain a chemical reagent system which works with the *Mission*® Hb Hemoglobin Meter to measure the hemoglobin (Hb) concentration in capillary and venous whole blood.

Each test strips appears as shown:

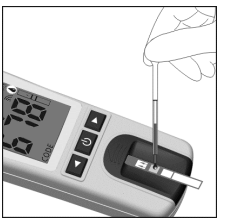


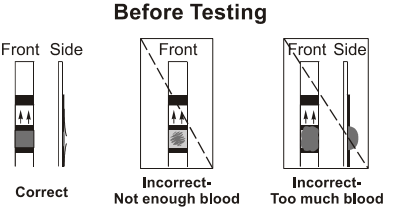
Specimen Application Area - After strip is inserted into the Strip Channel, apply 10 µL of blood to the center of the test strip. The Specimen Application Area is visible from the front and the back of the Test Strip.

Insert Arrows - Located on the front of the test strip, the arrows show the direction in which the test strip should be inserted.

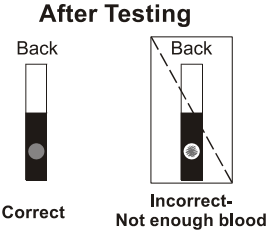
Specimen Application

For best results, fill the Specimen Application Area with approximately 10 µL of blood specimen. Incorrect results may occur if the specimen is not applied correctly, or if the Specimen Application Area is not filled.





After applying the specimen, ensure the Specimen Application Area is completely covered. The Specimen Application Area should remain covered throughout the entire test. If the Specimen Application Area is not covered, or if there is too much specimen covering the Specimen Application Area, repeat the test with a new test strip.



Note: Do not add more blood to the test strip if the specimen applied to the Specimen Application Area is too little. Error ***E-5*** or a low result may appear on the display. Discard the used strip and retest.

Code Number

Each package of test strips is printed with a code number CODE, lot number LOT, unopened expiration date and test quantity . Whenever a new canister is opened, mark the date on the label. Calculate the opened expiration date by adding three months. Record this opened expiration date on the label.

Test Strip Precautions and Instructions for Use

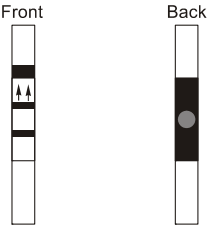
- Test Strips should be stored tightly capped in their protective canister to keep them in good working condition.
- Do not store test strips outside their protective canister. Test strips must be stored in the original canister with the cap tightly closed.
- Do not transfer test strips to a new canister or any other container.
- Replace the cap on the test strip canister immediately after removing a test strip.
- A new canister of test strips may be used for 3 months after first being opened. The opened expiration date is 3 months after the date the canister was first opened. Write the opened expiration date on the canister label after opening. Discard the canister 3 months after it is first opened. Usage after this period may result in inaccurate readings.
- For *in vitro* diagnostic use. Test strips are to be used only outside the body for testing purposes.
- Do not use test strips that are torn, bent, or damaged in any way. Do not reuse test strips.
- Before performing a hemoglobin test, make sure that the code number on the meter display matches the number shown on the test strip canister and on the code chip ink-jet printed.

Refer to the test strip insert for more details.

Control Strips

The *Mission*® Hb Hemoglobin Control Strips are thin plastic strips which work with the *Mission*® Hb Hemoglobin Meter to ensure the optical system is working properly. After the control strip is inserted into the meter, the optical system of meter detects the color intensity of the control strip. The meter displays ***YES*** or ***no*** to show whether the meter is functioning properly. Refer to Section 8 Optical Check for details.

The control strip appears as shown below:



Precautions

- Store in the closed canister at room temperature within 2-30°C (36 - 86ºF) and avoid exposing it to direct sunlight, extreme temperature or humidity.
- Control strips should be stored tightly capped in their protective canister to keep them in good working condition.
- Do not freeze or refrigerate.
- Keep the control strip clean and do not bend. Do not touch the test area of the strip.

Remove the control strip for immediate use. Put the control strip back and close the canister tightly immediately after use. Do not use contaminated, discolored, bent or damaged control strips.

- Do not use after the expiration date.
- For *in vitro* diagnostic use only.

Storage and Handling

- Store control strips in a cool, dry place. Store away from heat and direct sunlight.
- Transport and store in its closed canister within 2-30 ºC (36-86 ºF), less than 85% humidity.
- Do not freeze or refrigerate.
- Replace the cap on the control strip vial immediately after removing it from container.
- A new canister of control strips may be used for 1 year after first being opened. The opened expiration date is 1 year after the date the canister was first opened. Write the opened expiration date on the canister label after opening. Discard the canister 1 year after it is first opened. Usage after this period may result in inaccurate readings.

  Note: The expiration date is printed in a Year-Month-Date format.

Section 4 Initial Setup

Before testing, ensure the following procedures are followed.

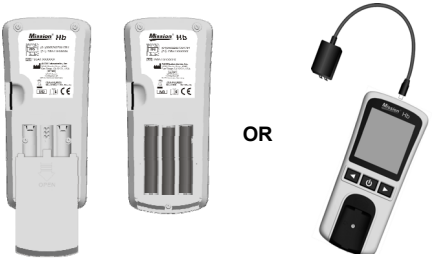
Turn on Meter

The meter can be operated using the certified AC Adapter or 3 AAA batteries (1.5V).

To use the meter with batteries, insert 3 AAA batteries (1.5V) into the battery compartment located on the back of the meter.

To use the meter with the power adapter, connect the Mini USB port of the power adaptor to the USB port located on the top of the meter with a USB cable, and plug the adaptor into a 100-240V ac, 50-60 Hz primary power outlet.

The meter can also be powered from the USB port of a personal computer, connected by a USB cable.



The meter will turn on automatically after the batteries are inserted. The meter will display the date and time setup screen. Refer to Section 5 Meter Setup for details. After the date and time have been set, the meter will automatically turn off.

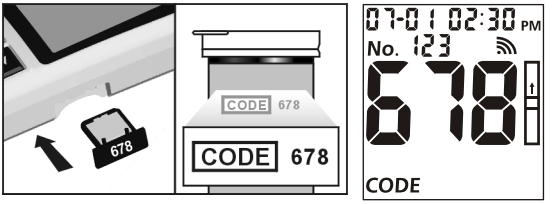
Press ⏻ to turn the meter on. The screen will briefly display all of the LCD symbols. Observe the LCD at startup to ensure all segments and display elements are turned on, and there are no missing icons or elements. After startup, observe there are no permanently turned on segments or icons. After the power-on diagnostic check, the Initial Screen will be displayed.

The meter will turn off automatically after 8 minutes of inactivity.

Coding the Meter

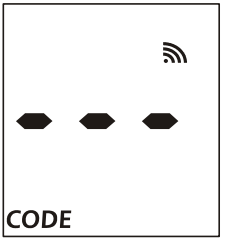
Each time a new box of test strips is used, the **code chip** packaged with the new box of test strips must be inserted into the meter. Take the **code chip** from the test strip box. Compare the code number on the **code chip** with the code number printed on the test strip canister label. Results may be inaccurate if the two numbers are not identical. For US customers, immediately call customer service toll free at 1-(800)-838-9502 if the code number on the code chip does not match the number on the test strip canister with which it was packaged. For customers outside the US, contact your local distributor immediately.

Insert the new **code chip** into the **code chip slot** of the meter. It should easily snap into place. The **code chip** should remain in the meter. Do not take it out until a new box of test strips is needed. The code number will appear on the Initial Screen after startup.



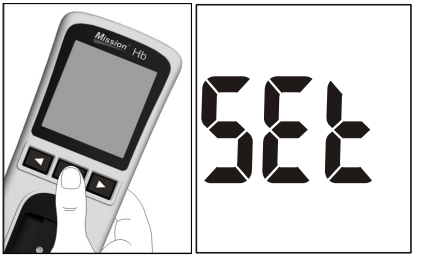
For US Customers, immediately call customer service toll free at 1-(800)-838-9502 if the code number on the **code chip** does not match the number that is displayed on the screen. For customers outside the US, contact your local distributor immediately.

If the **code chip** is not properly inserted into the **code chip slot**, or if it is missing, the meter will display ***three dashes*** as shown below.



Section 5 Meter Setup and Options

With the meter turned off, press and hold ⏻ for 4 seconds to enter **Meter Setup** mode shown below.



Press ◀ or ▶ to display several setup submodes:

No. SEt	Test number setup. The test number can be set from 1 to 999.
SEt	System setup, including date, time, test number reset, units and sound.
CHE	**Optical Check** mode. Refer to Section 8.
PC	**Data Transfer** mode. Refer to Section 7.
dEL	**Memory Delete** mode. Refer to Section 7.
Elt	Exit setup modes and save changes when ⏻ is pressed. The meter will automatically return to the Initial Screen.

Press ⏻ to enter the mode when the desired submode is displayed.

Test Number Setup

From the ***No. SEt*** screen, press ⏻ to enter **Test Number Setup**.

The test number can be set to any number from 1 – 999.

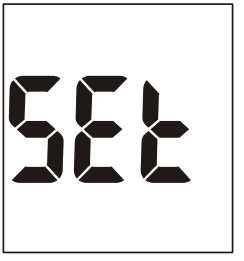
Press ◄ or ► until the correct test number is displayed. To quickly cycle to the desired test number, press and hold ◄ or ►.

Press ⏻ to save and return to the **Meter Setup** screen.

Note: Once the meter reaches test number 999, the next test number will be 1.

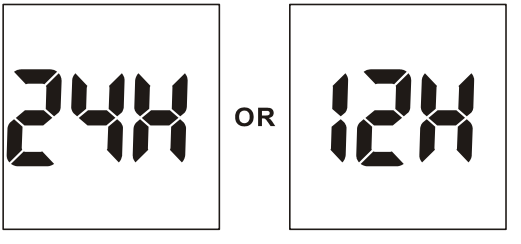
System Setup

From the ***SEt*** screen, press ⏻ to enter **System Setup**.



Hour Setup

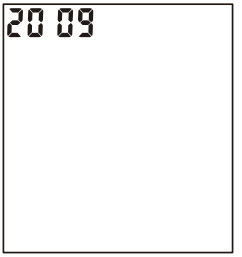
The first option sets the clock to either **12** or **24 hour** mode. Press ◄ or ► to switch between the two settings.



Press ⏻ to save and advance to **Year Setup**.

Year Setup

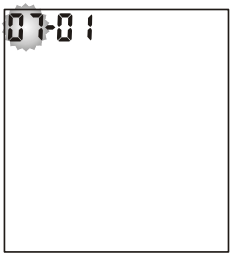
The year will appear at the top of the display. Press ◄ or ► until the correct year is displayed.



Press ⏻ to save and enter **Month and Date Setup**.

Month and Date Setup

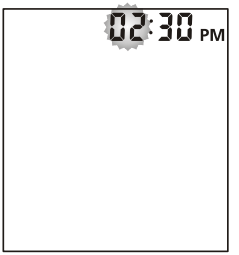
The month and date will appear at the top of the display separated by a single dash (**-**), with flashing month. Press ◄ or ► until the correct month is displayed.



Press ⏻ to save. The day will flash. Press ◄ or ► until the correct day is displayed, then press ⏻ to save and proceed to **Time Setup**.

Time Setup

The hour and minutes will appear at the top of the display separated by a colon, with flashing hour.



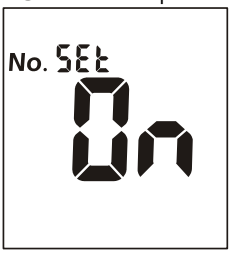
Press ◄ or ► until the correct hour is displayed. Press ⏻ to save and proceed to **Minutes**.

Note: The meter will display ***AM*** or ***PM*** if the 12H time setting is chosen.

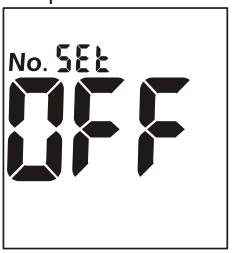
Minutes will flash. Press ◄ or ► until the correct **Minutes** are displayed. Press ⏻ to save and proceed to Test Number Reset Setup.

Test Number Reset Setup

Press ◄ or ► to turn the test number reset ***ON*** or ***OFF***. The test number will reset to 1 for each new day of testing when the test number reset is turned on. Press ⏻ to save and proceed to Units Setup.

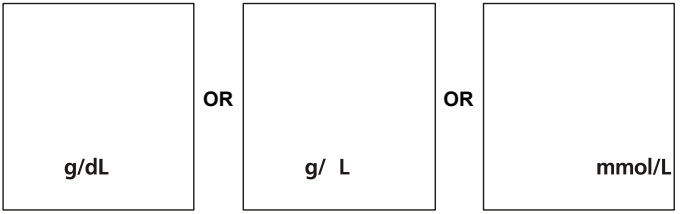


OR



Units Setup

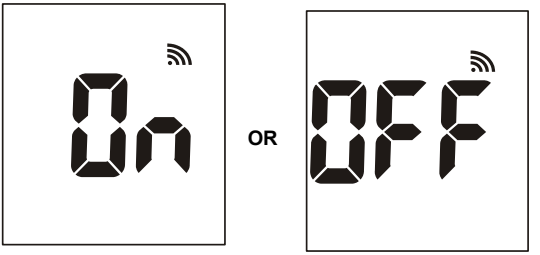
Press ◄ or ► to select either ***g/dL, g/L or mmol/L***.



Press ⏻ to save and proceed to **Sound Setup**.

Sound Setup

Press ◄ or ► to select sound either ***ON*** or ***OFF***. The ***Sound Symbol*** will appear on the display when the sound is turned on. Press ⏻ to save and return to the setup screen.



Press ◄ or ► until ***Elt*** is displayed and press ⏻ to exit setup. The screen will briefly go blank and display the Initial Screen.

Section 6 Testing

Before performing any test, the user should review the *Mission*® Hb Hemoglobin meter manual for detailed instructions. The following steps show how to use each component to measure the hemoglobin concentration.

Specimen Collection

The *Mission*® Hb Hemoglobin Meter requires a very small specimen which may be obtained from the whole blood. Fresh or EDTA or heparin-anticoagulated capillary or venous whole blood may be used. Before testing, choose a clean, dry work surface. Review the procedure and make sure all of the items needed to obtain a drop of blood are available.

Venous Blood Testing

For fresh whole blood venous specimens, collect the venous blood in a closed container with EDTA or heparin anticoagulants. Mix the specimen well, then collect approximately 10 µL into a plastic syringe or pipette. Apply it to the center of the Specimen Application Area of the strip. Do not touch the strip with the pipette.

- Whole Blood must be tested within 8 hours of collection.
- Mix the specimens well before testing in order to ensure the cellular components are evenly distributed.
- Allow the specimen to come to room temperature (15-30°C or 59-86ºF) for approximately 15 minutes if the specimen has been refrigerated.
- Anticoagulants other than EDTA are not recommended for use.

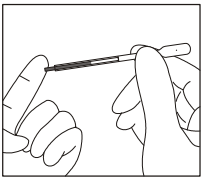
Note: Refer to NCCLS Documents H3-A6, Collection of Diagnostic Blood Specimens by Venipuncture.

Fingertip Blood Testing

Wipe away the first drop of blood. Apply light pressure to obtain a second drop of blood. Collect 10 µL of capillary blood using a Capillary Transfer Tube or pipette.

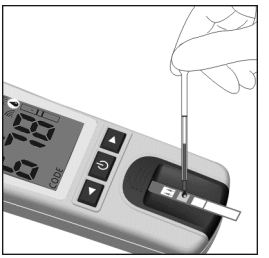
Note: Refer to NCCLS Documents H04-A6, Collection of Diagnostic Blood Specimens by Skin Puncture.

When drawing the blood sample into the capillary tube, it is important not to squeeze the bulb and/or cover the air vent. Holding the tube at a slightly downward angle, touch the tip of the capillary tube to the blood drop, The blood will automatically be drawn into the black fill line and stop. Make sure that blood reaches the black line, or it will be difficult to squeeze the blood out of the tube.



Note： Never squeeze the Capillary Transfer Tube and/or cover the air vent while collecting the blood sample.

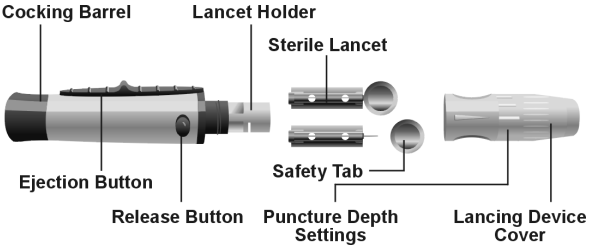
Align the tip of the Capillary Transfer Tube with the Specimen Application Area on the test strip. Squeeze the bulb and cover the air vent to apply the blood sample to the sample application area.



Note： Do not touch the strip with the Capillary Transfer Tube or pipette. The air vent should be covered while expelling the blood sample. The capillary blood should be tested immediately after collected. Use of a Capillary Transfer Tube or pipette is recommended for accurate results. Do not reuse the capillary transfer tube.

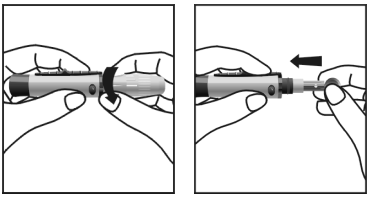
For REF C111-3021:

Blood specimens can also be obtained by using a lancing device. Refer to the instructions below for details.

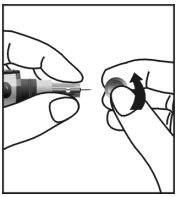


For obtaining a drop of blood from the fingertip, adjust the penetration depth on the lancing device to reduce discomfort.

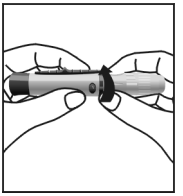
Unscrew the lancing device cover from the body of the lancing device. Insert a sterile lancet into the lancet holder and push it until the lancet comes to a complete stop in the lancet holder.



Hold the lancet firmly in the lancet holder and twist the safety tab of the lancet until it loosens, then pull the safety tab off the lancet. Save the safety tab for lancet disposal.

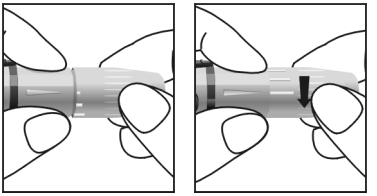


Carefully screw the cover back onto the lancing device. Avoid contact with the exposed needle. Make sure the cover is fully seated on the lancing device.



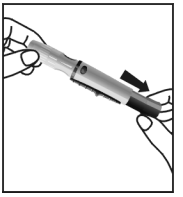
Adjust the puncture depth by rotating the lancing device cover. There are a total of 6 puncture depth settings. To reduce discomfort, use the lowest setting that still produces an adequate drop of blood.

Use settings 1 and 2 for delicate skin, 3 and 4 for normal skin, and 5 and 6 for calloused or thick skin.

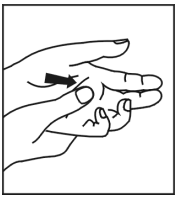


Note: Greater pressure of the lancing device against the finger will also increase the puncture depth.

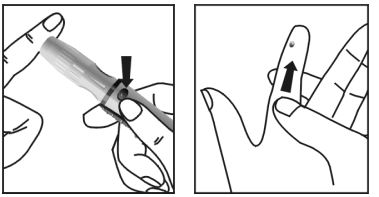
Pull the cocking barrel back to set the lancing device. A click may be heard. The device is now loaded and ready for obtaining a drop of blood.



Prior to testing, make sure the patient‘s hand is warm and relaxed before collecting the capillary blood specimen. Use warm water to increase blood flow if necessary. Massage the hand from the wrist up to the fingertip a few times to encourage blood flow.
Clean the testing site with an alcohol swab and then dry the testing site thoroughly.



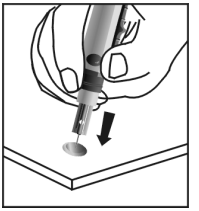
Hold the lancing device against the side of the finger to be lanced with the cover resting on the finger. Push the release button to prick the fingertip. A click should be heard as the lancing device activates. Gently massage from the base of the finger to the tip of the finger to obtain the required blood volume. Avoid smearing the drop of blood. For the greatest reduction in pain, lance on the sides of the fingertips. Rotation of sites is recommended. Repeated punctures in the same spot can make the fingers sore and callused.



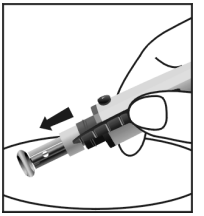
Note: Make sure the patient‘s hand is warm and relaxed before collecting a capillary blood specimen. Use warm water to increase blood flow if necessary.

Disposal of the Lancet

Unscrew the lancing device cover. Place the safety tab of the lancet on a hard surface and carefully insert the lancet needle into the safety tab.



Press the release button to make sure that the lancet is in the extended position. Slide the ejection button forward to eject the used lancet. Place the lancing device cover back on the lancing device.

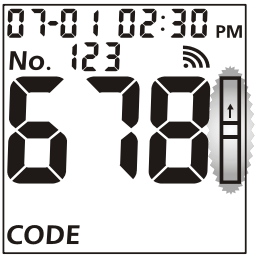


Strip Processing and Testing

Ensure the meter is set up properly as described in previous sections. Turn the meter on. The screen will briefly display all of the LCD symbols. Observe the LCD at startup to ensure all segments and display elements are turned on, and there are no missing icons or elements. The meter will briefly show a blank display. Observe there are no segments or icons permanently turned on.

After startup, the Initial Screen will be displayed. Ensure the code chip is inserted, and compare the number showed in the display with the code number printed on the test strip canister label. Refer to Section 4 Coding the Meter.

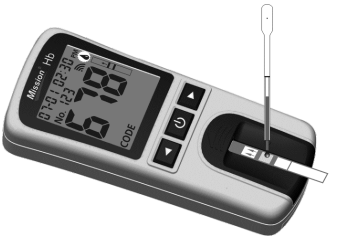
The ***strip symbol*** will flash when the meter is ready for the strip to be inserted.



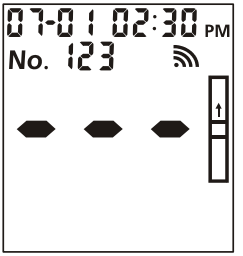
Testing

Insert a test strip into the strip channel in the same direction as the arrows indicated on the strip. Ensure that the test strip is inserted all the way to the end of the strip channel, until the white edge of the test strip above the black line is no longer visible.

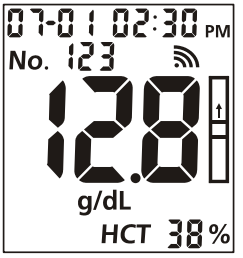
The ***blood drop symbol*** will flash when the meter is ready for the specimen to be applied. Apply approximately 10 µL of blood to the middle of the Specimen Application Area of the test strip.



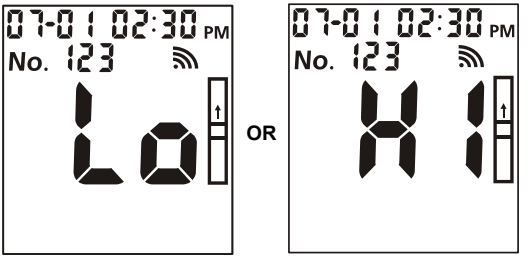
Note: For testing capillary blood, use the second drop of blood for accurate results. Refer to Section 6 Fingertip Testing for details. The meter will begin testing automatically with ***three dashes*** in a line flashing on the display indicating the test is in progress.



Hb results will be displayed within 15 seconds, with ***Hct*** value displayed at the bottom of the screen.



If the concentration of hemoglobin is less than 4 g/dL (40 g/L or 2.48 mmol/L), the meter will display ***Lo.*** The meter will display ***Hi*** if the concentration is more than 25.6 g/dL (256 g/L or 15.9 mmol/L).



Remove the used test strip. The meter will return to the initial screen ready for another strip to be inserted and a test to be performed.

Note: Discard all blood specimens, used test strips and materials carefully. Treat all blood specimens as if they were infectious materials. Follow proper precautions and obey all local regulations when discarding blood specimens and materials.

Perform daily cleaning when testing is completed for the day. Refer to **Section 10 Maintenance**.

The meter will automatically turn off after 8 minutes of inactivity, or when ⏻ is pressed. If the meter is powered with an AC adaptor, turn off the meter before removing it from the power outlet. Remove the batteries if the meter will not be used for an extended period of time.

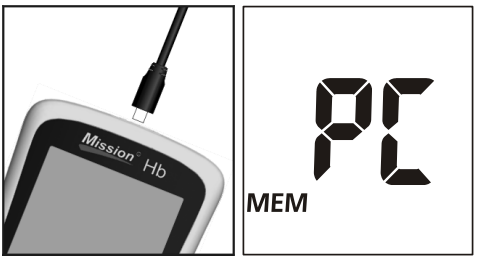
Section 7 Data/Communication

Data Transmission

Plug the USB cable into the USB port located on the top of the meter and connect the other end of the USB cable to a suitable PC.

Note: The PC must have suitable software installed to receive and process the data being transmitted from the meter.

From the Setup screen (refer to Section 5 Meter Setup), press ◄ or ► until ***PC*** is displayed. Press ⏻ to enable the Data Communication mode, ***MEM*** will be displayed.



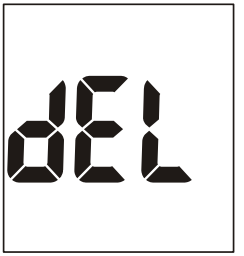
Press ⏻ to transmit data to an external certified PC.

After data transmission is complete, the meter will return to the Setup Menu.

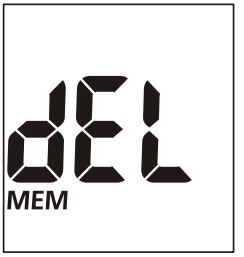
Note: Up to 999 test records are automatically stored in memory. After 999 test records are stored, the oldest test record will be replaced by a new record. For example, if 999 records are stored in memory, the next test result (1,000) will replace the first result stored in memory.

Deleting Data

To delete all data from the meter database, enter the Setup Menu (refer to Section 5 Meter Setup). Press ◄ or ► until ***dEL*** is displayed.



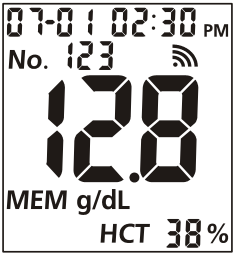
Press ⏻ to enable data deletion, ***MEM*** will be displayed.



Press and hold ⏻ until the meter returns to the Setup Menu.

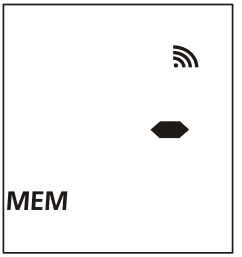
Memory/Database

From the Initial Screen (refer to Section 5 Meter Setup), press ◄ or ► to show the first record.



Press ◄ or ► to view each record in date/time sequence. Press and hold ⏻ to return to the Initial Screen.

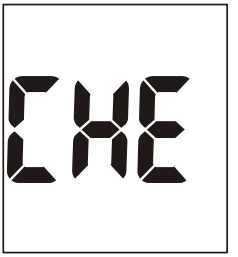
If no data is stored the meter will display ***one dash*** (**-**) and ***MEM***.



Section 8 Optical System Check

Optical Check

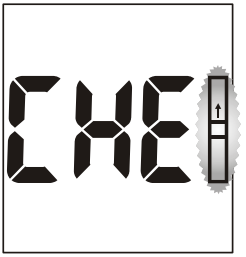
Press ◄ or ► from the Setup Screen to select the Optical Check mode as shown.



Note:

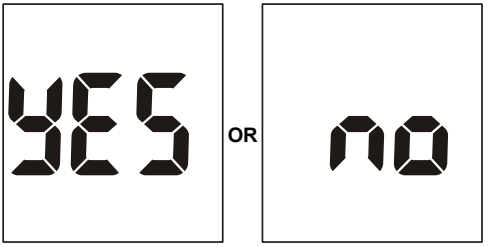
- The control strip is intended for checking the optical system. Refer to Section 9 Quality Control Test for using control solutions.
- Allow the strips and the meter to reach room temperature (15-30ºC or 59-86ºF) prior to testing.
- The optical check should be performed under normal lab lighting conditions. Do not perform under sunlight or extreme lighting conditions.

Press ⏻ to enter this mode. The meter will flash the strip symbol as shown below.



Insert a control strip into the strip channel in the same direction as the arrows indicated on the strip. Ensure that the test strip is inserted all the way.

Press ⏻ to start the optical check. If the meter displays ***YES***, the meter is normal. If the meter displays ***no***, the meter is not functioning properly.



If the meter displays ***no***, check the control strip for contamination or if it is bent or damaged. If there are any visible signs of damage or contamination, discard the control strip and retest using a new control strip.

Note: For US customers, call customer service toll free at 1-(800)-838-9502 if the meter displays ***no*** again. For customers outside the US, contact your local distributor to double check if any Problem with system.

Press ⏻ to return to the Setup Screen.

Section 9 Quality Control

Each lab should use its own standards and procedures for performance. Test known specimens/controls at each of the following events in accordance with local, state, and/or federal regulations or accreditation requirements.

- Each new day of testing
- A new canister of strips is opened
- A new operator uses the analyzer
- Test results seem inaccurate
- After performing maintenance or service on the analyzer

If QC tests do not provide expected results, perform the following checks:

- Ensure the strips used are not past their expiration date.
- Ensure strips are fresh from a new canister.
- Ensure the controls are not past their expiration date.
- Repeat the test to ensure no errors were made during the test.

For US customers, call customer service toll free at 1-(800)-838-9502 for additional information. For customers outside the US, contact your local distributor.

Section 10 Maintenance

Proper maintenance is recommended for best results.

Cleaning

For best results, the meter should be cleaned after each day of testing.

Meter Surface

A cotton cloth can be used to clean the surface of the meter. Use a damp cotton cloth if necessary.

A dry, soft cloth may be used to clean the LCD and the sensor area. It is recommended that the meter be stored in the carrying case after each use.

Take care to avoid getting liquids, residue, or control solutions in the meter through the **Strip Channel, Code Chip Slot** or **USB Port**.

Test Strip Holder

Remove the **Test Strip Holder** by pressing in on middle of the **Test Strip Holder** and sliding it out from the meter. Wipe it with a damp cloth or a mild detergent and dry it with a dry, soft cloth. Slide the **Test Strip Holder** back into the meter by laying it flat on the meter. Firmly press down on the center of the **Test Strip Holder** with your thumb and push it in until it clicks into place.

Note: Do not use organic solvents, such as gasoline or paint thinner. This will cause damage to the meter.

Meter Sensor Area

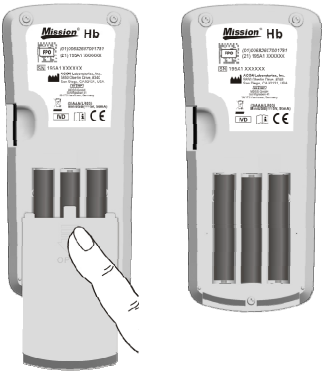
Remove the **Test Strip Holder** as described in the previous section. Wipe down the **Meter Sensor Area** with a cotton swab. Do not to scratch the transparent window covering the sensor.

Note: Do not use bleach or alcohol to clean the **Meter Sensor Area**. This will cause damage to the meter.

Replacing the Batteries

When the battery icon  is flashing, the battery is running low and should be replaced as soon as possible. An ***E-4*** error message will appear if the battery is too low to perform any more tests. The meter will not function until the battery is replaced.

Make sure the meter is off before removing the battery. Turn the meter over to locate the battery cover. Press the battery cover tab on the top and lift the cover to open it. Remove and discard the old batteries. Insert three AAA batteries on top of the plastic tape. Make sure the two outside batteries are aligned with the plus (+) side down, towards the bottom of the meter, with the middle battery aligned with the plus (+) side facing up, towards the top of the meter.



Close the battery cover and make sure that it snaps shut. Recheck and reset the clock setting as necessary after battery replacement to ensure time is set correctly. Refer to Section 4 Initial Setup.

Note: Do not discard batteries along with household waste. Follow local regulations for disposal.

Section 11 Precautions

Observe the precautions listed below to ensure accurate results and proper operation of the analyzer.

- The protection provided by the equipment may be impaired if used in a manner not defined in this instruction manual.
- Wear gloves to avoid contact with potentially hazardous biological specimens during testing.
- Avoid storing or operating the analyzer in direct sunlight, excessive temperature, or high humidity. Refer to Appendix 1 Meter Specifications for operating condition requirements.
- Keep the unit clean. Wipe it frequently with a soft, clean and dry cloth. Use fresh water when needed.
- Do not clean the unit with substances such as gasoline, paint thinner or other organic solvents to avoid any damage to the meter.
- Do not clean the LCD or sensor area with water. Lightly wipe with a soft, clean, dry rag.
- The Strip Channel must be kept clean. Lightly wipe with a soft, clean, dry rag each day. Use water as needed. Refer to Section 10 Maintenance.
- Follow all local regulations when discarding the unit or its accessories.
- Do not use the unit or the strips outside of the operating temperature ranges listed below.

  Analyzer: 10-40 ºC (50-104 ºF) ; ≤90％ RH

  Strips: 15-30 ºC (59-86 ºF) ; ≤85％ RH

Section 12 Troubleshooting

Display	Causes	Solution
E-1	The sensor area is damaged, dirty, or blocked at turn-on, such as a used test strip left in the meter.	Ensure the sensor area is clean and that there are no objects covering the sensor area. Refer to Section 10 Cleaning. Restart the meter. Contact your local distributor if the sensor area window is broken.
E-2	Test strip was removed during the test.	Repeat the test and ensure the test strip remains in place.
E-3	Specimen was applied to the test strip too soon.	Repeat the test and apply specimen after blood drop symbol appears.
	Batteries are discharged but have enough power to run 20 more tests.	Test results will still be accurate, but replace the batteries as soon as possible.
E-4	Batteries have discharged and meter will not allow more tests until discharged batteries are replaced.	Replace the batteries, or connect the meter to the AC Adapter, then repeat the test.
E-5	Insufficient specimen.	Repeat test and apply enough specimen. Use around 10 µL of whole blood.
E-6	Expired test strip.	Ensure the test strips are within the expiration date printed on the canister label.
E-7	Code chip was removed during testing.	Insert proper code chip. Confirm the code chip matches the test strip code and repeat the test.
Lo	The test result is lower than 4.0 g/dL (40 g/L or 2.48 mmol/L).	If the specimen was taken from a specimen container, ensure the specimen is mixed well and repeat test.
	Insufficient specimen less than 1µL	Repeat test and apply enough specimen. Use around 10 µL of whole blood.
Hi	The test result is higher than 25.6 g/dL (256 g/L or 15.9 mmol/L).	If the specimen was taken from a specimen container, ensure the specimen is mixed well and repeat test.
--- CODE	No code chip in the meter; Code chip is damaged or inserted incorrectly.	Insert the code chip that accompanied the box of test strips. If the code chip is damaged, use a new code chip with the correct code number. If the code chip is inserted incorrectly, remove the code chip and insert it into the code chip slot.

For US customers, call customer service toll free at 1-(800)-838-9502 for details. For customers outside the US, contact your local distributor.

Appendix 1 Meter Specifications

Feature	Specifications
Methodology	Reflectance Photometer
Test Time	<15 seconds
Measurement Range	4.0-25.6 g/dL, 40-256 g/L, 2.48-15.9 mmol/L
Specimen	Whole blood
Specimen Volume	10 µL
Power Source	3 AAA batteries (1.5V) AC Adapter (Mini USB, 5V dc, 50 mA)
Battery Life	360 hours or 2,700 tests
Units of Measure	g/dL, g/L, mmol/L
Memory	1,000 records
Automatic Shut Off	8 minutes after last use
Meter Size	127 mm × 58 mm × 25 mm (5.0” × 2.28” ×0.09”)
Display Size	39 mm × 37 mm (1.54” ×1.46”)
Weight	102 g (without batteries)
Meter Storage Conditions	0 - 50 ºC (32 -122 ºF); ≤90％ RH
Operating Conditions	10 - 40 ºC (50 -104 ºF); ≤90％ RH
Meter Connectors	USB cable for Data Transfer or Power (optional)

Appendix 2 Index of Symbols

	Consult instructions for use		*In vitro* diagnostic medical device
	Catalogue number		Serial Number
	Manufacturer		Authorized representative in the European Community
	Lot Number		Use by
	Contains sufficient for <n> tests		Temperature limit
	Sterilized using irradiation		Code Number
	Do not discard along with household waste		USB Port
	Fragile, handle with care		This Side Up
	Keep away from sunlight and heat		Keep Dry
	Do not reuse		

Appendix 3 Warranty

Please complete the warranty card included in the packaging. Mail it to your local distributor to register your purchase within one year of purchase.

For your records, write the purchase date of your starter kit here:

Note: This warranty applies only to the meter in the original purchase. It does not apply to the other materials included with the meter.

ACON Laboratories, Inc. warrants to the original purchaser that this meter will be free from defects in materials and workmanship for a period of two years (24 months). The two years starts from the later of the date of original purchase or installation (except as noted below). During the stated two years period, ***ACON*** shall replace the meter under warranty with a reconditioned meter or, at its option, repair at no charge a meter that is found to be defective. ***ACON*** shall not be responsible for shipping charges incurred in the repair of a meter.

This Warranty is subject to the following exceptions and limitations:

This warranty is limited to repair or replacement due to defects in parts or workmanship. Parts required which were not defective shall be replaced at additional cost. ***ACON*** shall not be required to make any repairs or replace any parts that are necessitated by abuse, accidents, alteration, misuse, neglect, failure to operate the meter in accordance with the user's manual, or maintenance by anyone other than ***ACON***. Furthermore, ***ACON*** assumes no liability from malfunction or damage to meters caused by the use of strips other than strips manufactured by ***ACON***. ***ACON*** reserves the right to make changes in the design of this meter without obligation to incorporate such changes into previously manufactured meters.

Disclaimer of Warranties

This warranty is expressly made in lieu of any and all other warranties express or implied (either in fact or by operation of law) including the warranties of merchantability and fitness for use, which are expressly excluded, and is the only warranty given by ***ACON***.

Limitations of Liability

In no event shall ***ACON*** be liable for indirect, special or consequential damages, even if ***ACON*** has been advised of the possibility of such damages.

For warranty service, please contact your local distributor.