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.

Digitally signed by Dolgopol Iulian
Date: 2024.07.17 12:38:24 EEST
Reason: MoldSign Signature
Location: Moldova

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

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

TÜV SÜD 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

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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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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

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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

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TÜV®

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

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

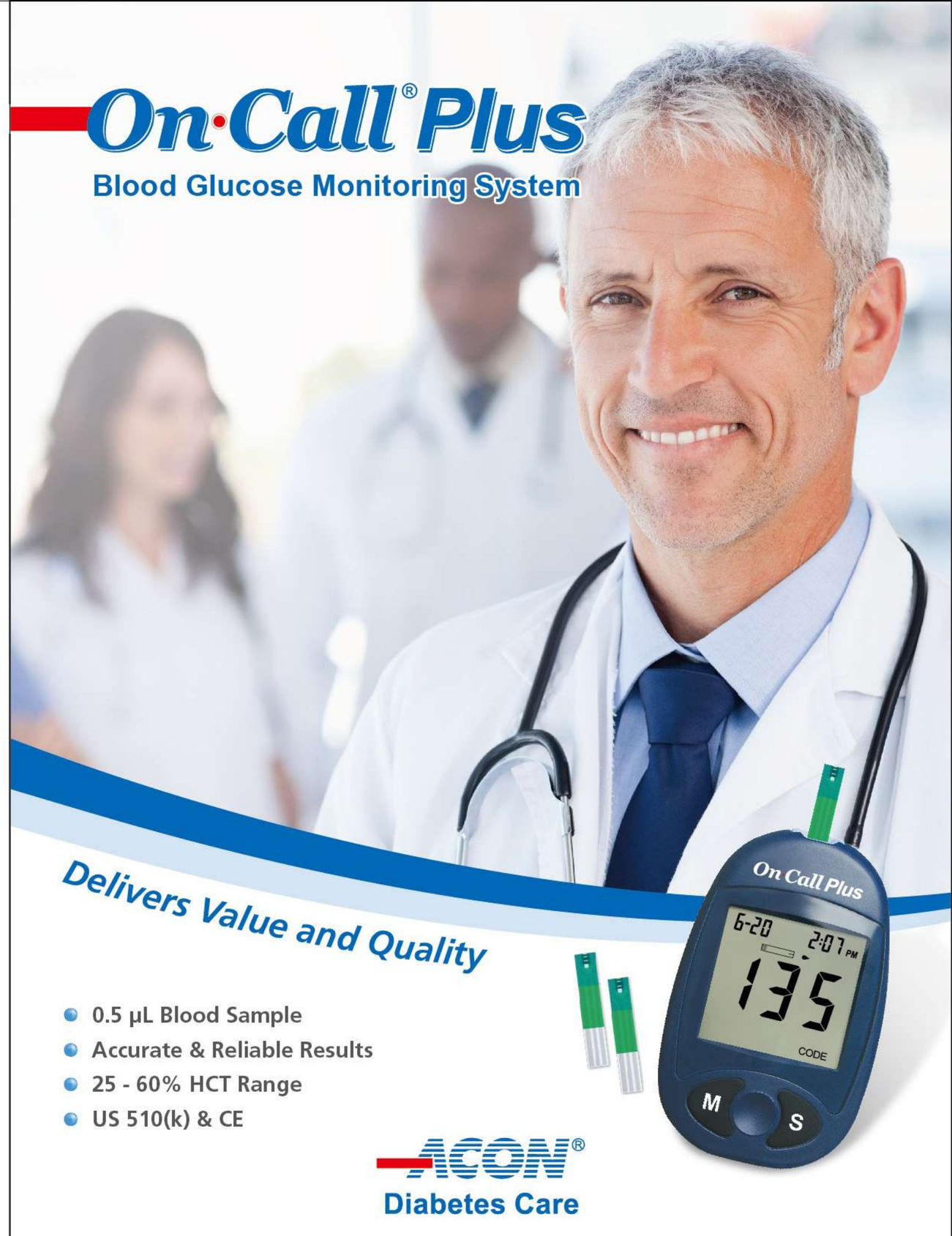
***ACON* Laboratories, Inc.**, 10125 Mesa Rim Road, San Diego, CA 92121, USA • Tel: 1-858-875-8000 • Fax: 1-858-200-0729 • E-mail: info@aconlabs.com

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

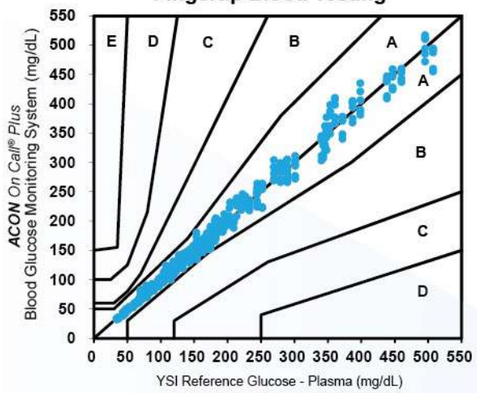
On·Call® Plus

Blood Glucose Monitoring System

Accurate and Reliable

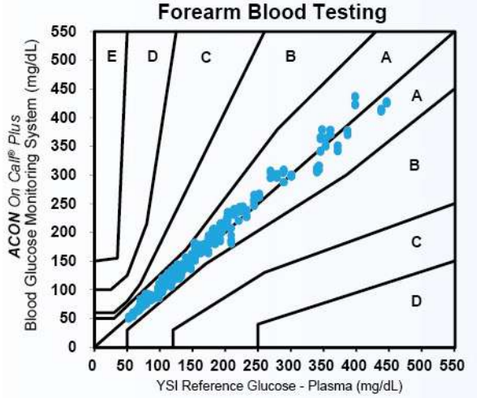
Extensive clinical studies proved the accuracy of *On Call® Plus* Blood Glucose Monitoring System with fresh capillary blood samples, which can comply with **EN ISO 15197: 2015**.

Fingertip Blood Testing



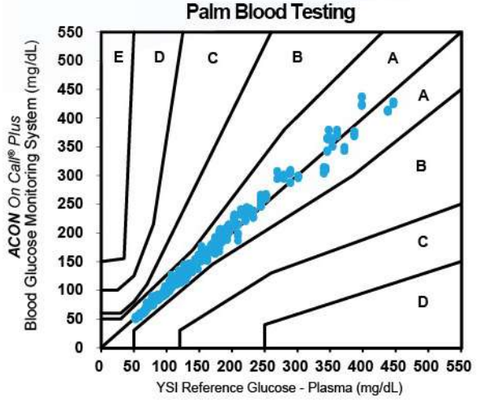
Consensus Error Grid Analysis Clinical Trial - Fingertip Capillary Blood, by Technican *ACON On Call® Plus* Blood Glucose Monitoring System vs. YSI		
System Accuracy Results for Glucose Concentration ≥ 100 mg/dL		
Within ±5%	Within ±10%	Within ±15%
290 / 462 (62.8%)	432 / 462 (93.5%)	462 / 462 (100.0%)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

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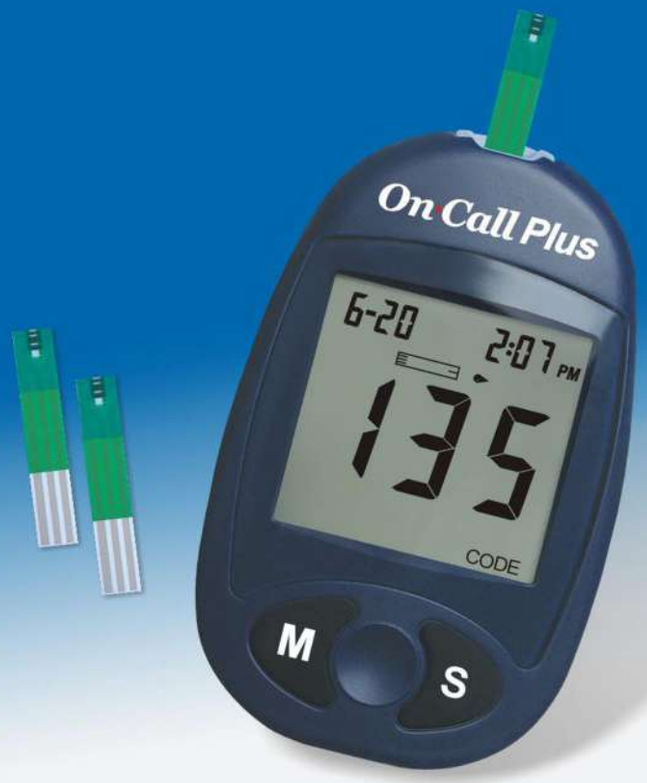
San Diego, CA 92121
888-882-7739

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

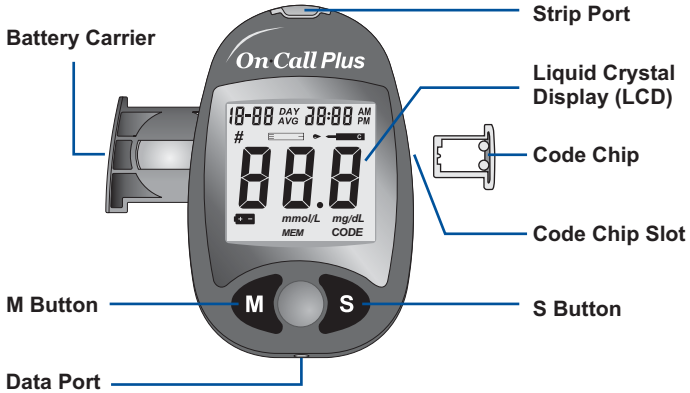
Carrying Case

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.

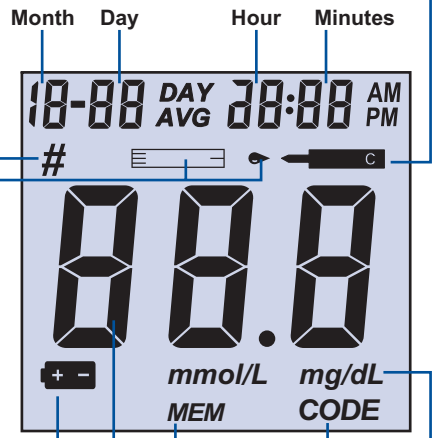
Code Chip: For coding the meter. A new code chip comes with every box of test strips.

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

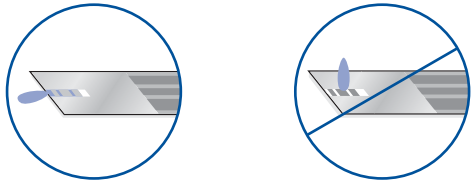
The *On Call® Plus* Blood Glucose Test Strips are thin strips with a chemical reagent which work with the *On Call® Plus* Blood Glucose Meter to measure the glucose concentration in whole blood. After the strip is inserted into the meter, blood is applied to the sample tip of the test strip, then automatically 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.

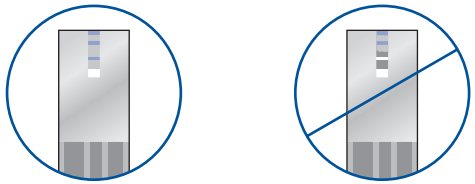
Contact Bars
Insert this end of the test strip into the meter until it stops.

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.



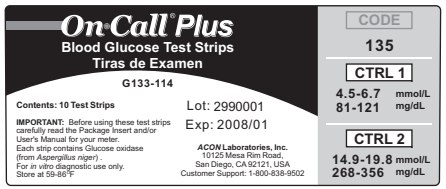
Correct **Incorrect**

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.

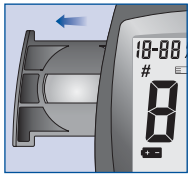
Please contact Customer Support at 1-800-838-9502 for more information on obtaining the control solution kit.

See the control solution insert for more details.

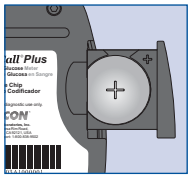
Install the Battery

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:

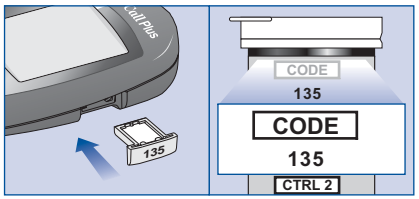
Step 1 - Coding the Meter

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.

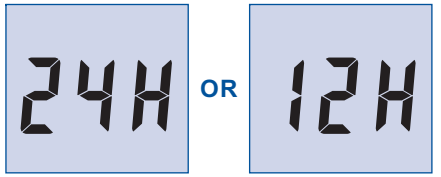


Note: If a test strip is inserted and no strip code is stored in memory, the display will flash "- - - CODE".

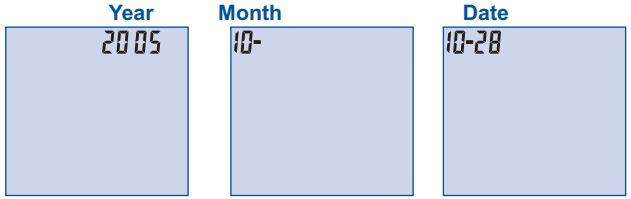
Step 2 - Adjusting the Meter Settings

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.

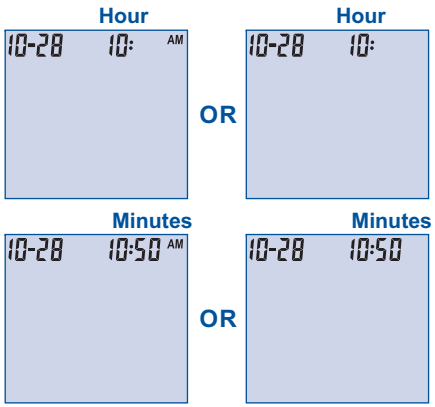
1. Press the S button to enter the meter setup mode. The meter will automatically enter the setup mode when turned on for the first time by any method.
2. First, set the clock for either 12 or 24 hour mode. Press the M button to switch between the two settings, then press the S button to save your choice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



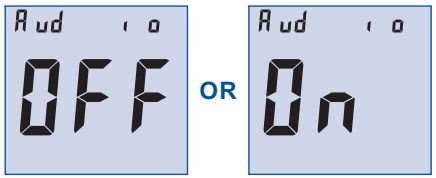
3. The year will appear at the top of the display. Press the M button until the correct year is displayed. Once you have selected the correct year, press the S button to save your choice and start setting the month. Press the M button until the correct month is displayed, then press the S button to save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

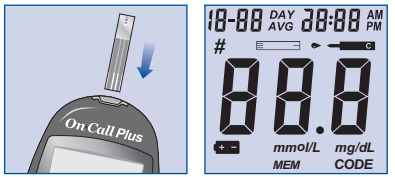


Performing a Quality Control Test

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:

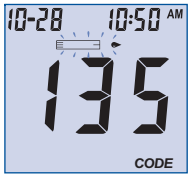
- Before you first use your meter.
- Before using a new box of test strips.
- When you suspect that the meter or test strips are not working properly.
- When you suspect that your test results are inaccurate, or if they are inconsistent with how you feel.
- When you suspect your meter is damaged.
- At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



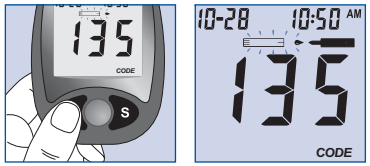
2. Check the display to confirm that all the display segments turn on (see display illustration above).

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.



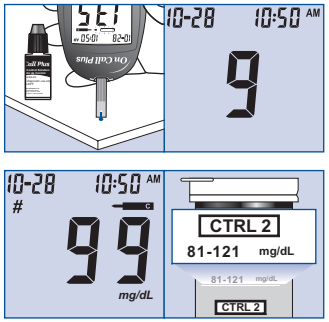
   The blinking test strip and blood drop icon indicates that the test strip is inserted correctly and a drop of control solution can be added.
   Note: If the test strip has been inserted incorrectly, the meter will not turn on.

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.

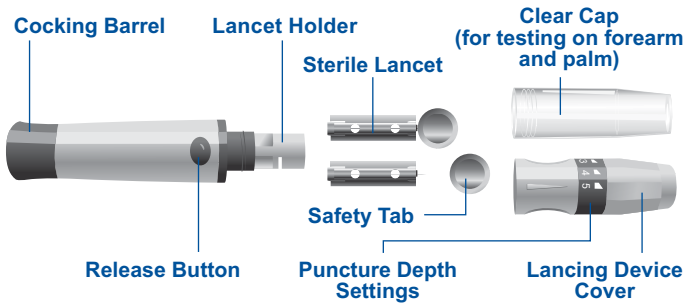
Testing Your Blood

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.

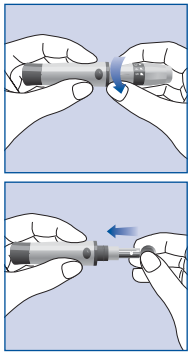
IMPORTANT: Prior to testing, wipe the test site with an alcohol swab or soapy water. Use warm water to increase blood flow if necessary. Then dry your hands and the test site thoroughly. Make sure there is no cream or lotion on the test site.



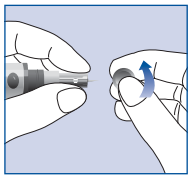
Fingertip Testing

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

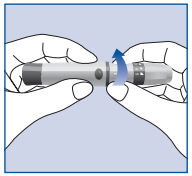
1. Unscrew the lancing device cover from the body of the lancing device. Insert a sterile lancet into the lancet holder and push it until the lancet comes to a complete stop in the lancet holder.



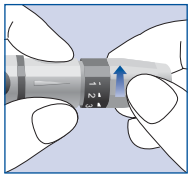
2. Hold the lancet firmly in the lancet holder and twist the safety tab of the lancet until it loosens, then pull the safety tab off the lancet. Save the safety tab for lancet disposal.



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.

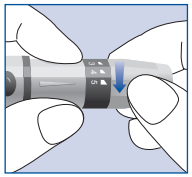


4. Adjust the puncture depth by rotating the lancing device cover. There are a total of 5 puncture depth settings. To reduce the discomfort, use the lowest setting that still

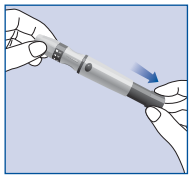


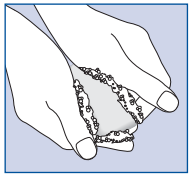
produces an adequate drop of blood.

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.

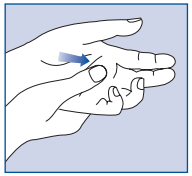


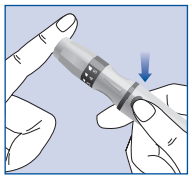
5. Pull the cocking barrel back to set the lancing device. You may hear a click. The device is now loaded and ready for obtaining a drop of blood.





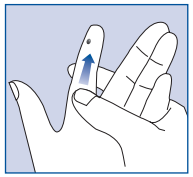
6. Prior to testing, wipe your hand with an alcohol swab or wash your hands with soap. Use warm water to increase blood flow in your fingers if necessary. Then dry your hands thoroughly. Massage the hand from the wrist up to the fingertip a few times to encourage blood flow.





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

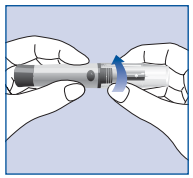
The forearm and palm areas have fewer nerve endings than the fingertip so you may find that obtaining blood from these sites is less painful than from the fingertip. The technique for forearm and palm sampling is different. You need the clear cap to draw blood from these sites. The clear cap is not adjustable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

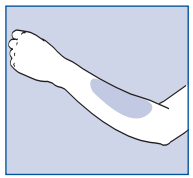
Please refer to **Fingertip Testing** to insert the lancet and load the lancing device.

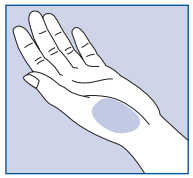
1. Screw the clear cap onto the lancing device.



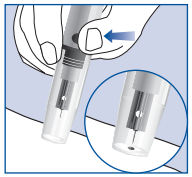
2. Choose a puncture site on the forearm or palm. Select a soft, fleshy area of the forearm that is clean and dry, away from bone, and free of visible veins and hair.

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.



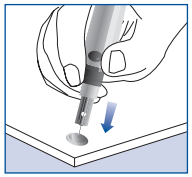


3. Place the lancing device against the puncture site. Press and hold the clear cap against the puncture site for a few seconds. Press the release button of the lancing device, but **do not immediately lift the lancing device** from the puncture site. Continue to hold the lancing device against the puncture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

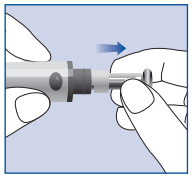


Disposal of the Lancet

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.

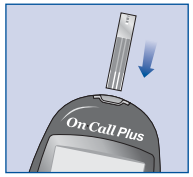
Specimen collection and preparation by healthcare professionals

Please refer to test strip insert if applicable.

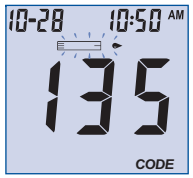
Step 2 - Testing Blood Glucose

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.

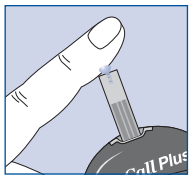


Make sure that the code number that appears on the display matches the code number (CODE) on the test strip vial (or on the foil pouch). If not, make sure to locate and insert the code chip that came with the box of strips. If the codes still do not match, do not perform a test. You will need a new package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



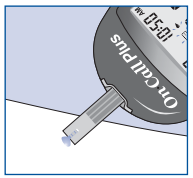
2. The blinking test strip and blood drop icon will indicate that the test strip is inserted correctly and a drop of blood can be added.

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.

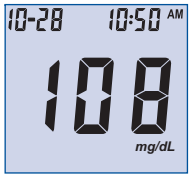


DO NOT:

- 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.

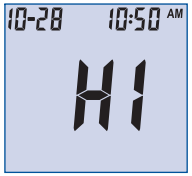
5. After inspection, record valid results in your logbook with the date and time, and compare them to the target goals set by your healthcare professional. Refer to **Suggested Testing Times and Target Goals** on page 29 and your logbook for more details on your target blood glucose concentration goals.

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.

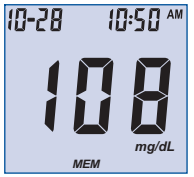
Using the Meter Memory

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.

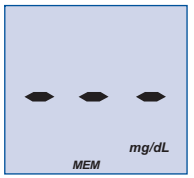
Viewing Stored Records

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.

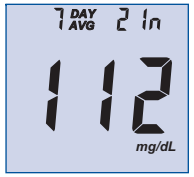


2. The date and time will be displayed together with the results stored in memory. A pound sign (#) indicates records that will be omitted from the 7, 14 and 30 day averages.

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.

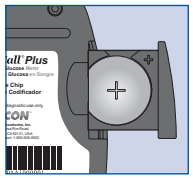
Maintenance

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

TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993

CONCERNING MEDICAL DEVICES

Version 1.4 FS-CE-04

MANUFACTURER: SHENZHEN FITFAITH TECHNOLOGY CO., LTD.

501, Building B5, DongfangJianfuYijing Industrial City, Tianliao Community, Yutang Street, Guangming District, Shenzhen

EUROPEAN REPRESENTATIVE: LOTUS NL B.V

Koningin Julianaplein 10, le Verd, 2595AA, The Hague, Netherlands

PRODUCT: PULSE OXIMETER F380, F380A

CLASSIFICATION: CLASS II A, RULE 10 ACCORDING TO ANNEX IX OF THE MDD 93/42/EEC

CONFORMITY ASSESSMENT ROUTE: ANNEX II.3

WE HEREBY DECLARE THAT THE ABOVE MENTIONED DEVICES COMPLY WITH THE LEGISLATION OF MEMBER STATES AT DAVY AVENUE, KNOWLHILL MILTON KEYNES MK5 8NL, UNITED KINGDOM TRANSPOSING EUROPEAN MEDICAL DEVICE DIRECTIVE 93/42/EEC. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: SEE ATTACHED LIST OF STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.

NOTIFIED BODY: INTERTEK SEMKO AB

IDENTIFICATION NUMBER: CE 0413

(EC) CERTIFICATE(S): 41371470-03

START OF CE-MARKING: 17 MAY 2021

PLACE, DATE OF ISSUE: SHENZHEN, CHINA, 17 MAY 2021

SIGNATURE: _____

YUAN JUNFENG GENERAL MANAGER

ATTACHED: *LIST OF STANDARDS*

#	NO./Edition	Standards Title
1	MDD 93/42/EEC &2007/47/EC	COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices
2	ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
3	EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
4	EN 60601-1:2006+A1:2013+ AC:2014+A12:2014 +A2:2020	Medical electrical equipment -Part 1: General requirements for basic safety and essential performance
5	EN 60601-1-2:2015+A1:2020	Medical electrical equipment -Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances -Requirements and tests
6	EN ISO 80601-2-61:2019	Medical requirements for the basic safety and essential performance of pulse oximeter equipment
7	EN 60601-1-11:2015+A1:2020	Medical electrical Equipment-Part 1-11: General requirements for basic safety and essential Performance-Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
8	EN ISO 15223-1:2016	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied
9	ISO 20417:2021	Information supplied by the manufacturer with medical devices
10	EN 62304:2006+A1:2015	Medical device software. Software life-cycle processes
11	EN 62366-1:2015+AC:2015+ AC:2016+A1:2020	Medical devices -Part 1: Application of usability engineering to medical devices
12	ISO 10993-1:2018	Biological evaluation of medical device- part 1: Evaluation and testing
13	ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
14	ISO10993-10:2021	Biological evaluation of medical devices — Part 10: Tests for skin sensitization
15	ISO10993-23:2021	Biological evaluation of medical devices — Part 23: Tests for irritation
16	MEDDEV 2.7.1: 2016 rev.4	Clinical evaluation: a guide for manufacture and notified bodies
17	YY 0784-2010	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use
18	(EU) 2017/745	REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017

intertek
Total Quality. Assured.

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Shenzhen Fitfaith Technology Co., Ltd.

Main Site: 501, Building B5, Dongfang Jianfu Yijing Industrial City, Tianliao Community, Yutang Street, Guangming District, Shenzhen, P.R. China

has been registered by Intertek as conforming to the requirements of:

ISO 13485:2016

The management system is applicable to:

Design and manufacture of pulse oximeters.

Certificate Number:
0076287

Revision Level: 02

Initial Certification Date:
3 June 2018

Date of Certification Decision:
23 May 2024

Issuing Date:
23 May 2024

Valid Until:
2 June 2027

ISO 13485:2016 CERTIFICATION ™
intertek

SCC Accredited CB-MS
OCSM Accrédité CCN ™
The SCC Accreditation Symbol is an official symbol of the Standards Council of Canada, used under licence.

Calin Moldovean
President, Business Assurance

Intertek Testing Services NA, Inc. dba Intertek
4700 Broadmoor SE, Suite 200
Kentwood, Michigan 49512, United States

Handheld Pulse Oximeter F380

Protable and Light weight

Care for others, care for health

Application

Pulse Oximeter can detect SpO2 and pulse rate through finger. The F380 handheld pulse oximetry is suitable for hospital' s operation room, clinic section office, out-patient department, sickroom, emergency treatment, and the recovery and health care organizations, or in the family nursing and in the process of transporting patients. Etc

- Easy and simple operation
- Low power consumption
- Display SpO2, PR,Bargraph and Plethysmogram
- Low battery indicator
- 2.8 inch TFT LCD, Adjustable Lightness
- Friendly menu
- Suitable for Adult,Pediatric,Neonate
- Two kinds of temperature optional, degrees Celsius, Fahrenheit
- Multi-language: English,Chinese,German,Spanish,Italian, Polish,Czech and Russian languages are currently supported

SpO2

Range: 35%-100%

Resolution: 1%

Accuracy:

80%-100% ±2%

70%-80% ±3%

<70% unspecified

PR

Range: 25 - 250bpm

Resolution: 1%

Accuracy: ±2bpm

Temperature(optional)

Range: 20 - 50°C

Resolution: 1%

Accuracy: ±0.2°C

Adult SpO2 Sensor

Child SpO2 Sensor

Neonatal SpO2 Sensor

CE ISO

F380 series

HANDHELD PULSE OXIMETER

USER'S MANUAL

VER 1.0

Shenzhen Omnihealth Technology Co., Ltd

2014/11

Chapter 1. Instructions

This manual provides the instructions necessary to operate Pulse Oximeter (hereinafter called as the Oximeter) in accordance with its function and intended use. Observance of this manual is a prerequisite and correct operation, and ensures patient and operator safety.

This manual is an integral part of and should always be kept close to the Oximeter, so that it can be obtained conveniently when necessary.

Content of this manual is subject to change without prior notice.

Issued date: 2014.09.08

Version: 1.0

Statement

The manufacturer is responsible for safety, reliability and performance of this product only in that:

- All installation operations, expansions, changes, modifications and repairs of this product are conducted by manufacturer authorized personnel; and
- The electrical installation of the relevant room complies with the applicable national and local requirements; and
- This product is operated under strict observance of this manual.

Guarantee

Free service scope

- The manufacturer provides free service to any product which conforms to the warranty regulations.

Chargeable service scope

- The manufacturer charges customers for service to any product which is outside warranty regulations' range.
- The manufacturer's obligation or liability under his warranty does not include the service of any factitious damage. Or the voltage of power supply network beyond the product's specification, or irresistible natural disaster, or delay resulting from the improper use or application of the product, or the use of parts or accessories not approved by the manufacturer, or repairs by people other than the manufacturer authorized personnel.

Return Policy

In the event that it becomes necessary to return to the manufacturer, please obtain a return authorization first. Please contact the manufacturer's Service Department and provides the model number, serial number, and a brief description of the reason for return. Return shipments will not be accepted if the serial number is not clearly visible.

The customer is responsible for freight charges when this product is shipped to the manufacturer for service (including any relevant customs fees or other freight related charges).

Chapter 2. Safety Information

The safety statements presented in this chapter refer to the basic safety information that the operator of the oximeter shall pay attention to and abide by, There are additional safety statements in other chapters or sections, which may be the same as or similar to the followings, or specific to the operations.
The following safety terms warning and caution are used throughout this manual to point out hazards and to designate a degree or level or seriousness.

WARNING

Indicates a potential hazard situation or unsafe practice that, if not avoided, could result in death or serious injury.

CAUTION

Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.

NOTE

Provides application tips or other useful information to that you get the most from your product.

2.1 Warnings

- The oximeter is intended only as an adjunct in patient assessment. It is not intended as a device used for treatment purposes.
- The oximeter is intended for use only by qualified clinical physicians or well-trained nurses.
- To ensure patient safety, verify this device and accessories can function safely and normally before use.
- When using the oximeter together with the electrical surgery equipment, the user should pay attention to and guarantee safety of the patient being measured.
- EXPLOSION HAZARD: Do not use the oximeter in the presence of flammable anesthetics, explosive substances, vapors or liquids.
- Do not pull or lift the oximeter by its connection cable. That may lead to falling and consequent patient injuries.
- It is not recommended to hang the oximeter when transporting patients. Safety hazards may arise from the large amplitude swing during the transportation.
- Make sure not to use the oximeter and it's transducer during MRI (magnetic resonance imaging) scanning because induced current could potentially cause burns. The oximeter is capable of interfering with the proper performance of MRI, and MRI is capable of interfering with the

measurement accuracy of the oximeter.

- The oximeter and its accessories may be contaminated by microorganism during transporting, use and storage. Use the recommended methods to sterilize and disinfect the oximeter or its accessories when the packing material is damaged, or it has not been used for a long time.

2.2 Cautions

- The oximeter is a commonly sealed device. Keep its surface dry and clean, and prevent any liquid from infiltrating it.
- The device should be appropriately placed. Keep it from falling, strong vibration or other mechanical damage.
- The oximeter should only be maintained by personnel approved by our company.
- Before using the oximeter on patients, the user should be familiar with its operation.

2.3 Notes

- Important! Before use, carefully read this manual, all safety information and specifications.

Chapter 3. General

3.1 Introduction

The oximeter is a non-invasive, handheld patient Oximeter. It operates on alkaline or rechargeable battery power supply. It is compact, small, light, and easy for learning and handling. It is suitable for monitoring adult and child patients. It is widely used in the hospital's operation room, ICU, clinic section office, out-patient department, sickroom, emergency treatment, and the recovery and health care organizations, or in the family nursing and in the process of transporting patients.

Parameters measured by the oximeter include: arterial oxygen saturation (SpO2), pulse rate (PR), bargraph and plethysmogram. The oximeter measures these parameters through a SpO2 sensor and displays them on the color TFT LCD screen after certain further processing.

The oximeter is operated and controlled by the buttons on the front panel. It adopts a 2.8 inch color TFT LCD screen in displaying measurements and in supplementary status indication.

3.2 Features

- Lightweight for carrying and Easy-To-Use.
- Silicon rubber shell protection and stable bracket for table usage.
- Using DB9 type connector compatible with Nellcor Spo2 Sensor.
- Support the oximeter probe for adult, neonate and infant.
- Big size 2.8 inch color TFT LCD display for SPO2/PR/Pulse bargraph/ plethysmogram.
- Visual and sound alarm function.
- Adjust the parameters in friendly menu.
- Low Battery voltage indicator.
- Automatically switch off within 3 minutes when no signal.
- Inner Flash memory can store testing result up to 360 hours.
- USB interface support upload the data to computer and review the history data with software in PC.
- Standard 4X AAA 1.5V Alkaline battery or rechargeable Li battery is available for power supply

3.3 Appearance

Figure 3-1 Front Panel

Figure 3-2 Back Panel

Figure 3-3 Top Side Panel

Figure 3-4 Right Side Panel

Table 3-1 Appearance description

No.	Description	Remarks
1	LCD display	It displays test result& information, as described in chapter 5.
2	Power on indicator	It displays the power on situation of the machine.
3	Power button	It turns on or off the device power.
4	Menu button	It turns on the menu setting and act as confirm function in the menu.
5	Battery charger Light	It displays the charge situation of the battery. Green light for on charge, Red light for charging full.

6	Mute Button 	It turns on or off the sound of alarm and beep of pulse sound.
7	UP button 	It changes the parameter along up direction.
8	EXIT button 	It confirms the selection parameter and exit the submenu.
9	DOWN button 	It changes the parameter along down direction.
10	Speaker	It ring the alarm sound when the test value beyond the limit and the
11	Bracket socket	It can install a steel bracket
12	Battery compartment	It use 4 AAA Alkaline battery or 3.6V Li battery
13	SpO2 probe socket	It connects SpO2 sensor.
14	Temperature sensor socket	It connects temperature sensor.(optional)
15	USB port	It connects the computer for data transfer.

Chapter 4. Installation

4.1 Unpacking and Inspection

Please open the package and remove the instrument and accessories carefully. Check all materials against the packing list.

- Check the oximeter for any mechanical damage.
- Check exposed wires, sockets and the accessories.

Contact supplier immediately in case of any problem.

WARNING

- Be sure to keep the packaging materials from children's reach.
- Disposal of the packaging materials shall comply with your local requirements.

NOTE

- Please save the packing case and packaging material for future transport and storage.

4.2 Connect SpO2 Sensor

You can connect the SpO2 sensor to the oximeter by simply inserting their connectors to the SpO2 socket on the Oximeter's top side panel as shown in figure 3-3.

4.3 Connect temperature sensor. (Optional)

You can connect the temperature sensor to the Oximeter by simply inserting their connectors to the temperature sensor socket on the Oximeter's top side panel as shown in figure 3-3.

4.4 power-on

Press the power button  and hold for more than 1 second to turn on the Oximeter, the LCD display lights up on the front panel and the screen displays SpO2 and PR parameter monitoring interface.

Chapter 5. Display and Operation

The screen of the Oximeter (Display Area) can display the monitoring parameters. The buttons on the front panel operate the Oximeter below this screen. For button details, please refer to figure 3-1 and table 3-1.

5.1 Power-on and Power-off

Press the power button  and hold for more than 1 second to turn on the oximeter. The LCD lights up on the front panel and the screen appear display. When the oximeter is on, press the power button to turn off the oximeter.

Note

- The oximeter is powered by the 4 AAA alkaline batteries or 3.6V Li recharge battery. If the battery power is not enough, the Oximeter may fail to be turned on. It should replace the new battery and the machine will be work.
- In case the SpO2 sensor becomes disconnected, or the SpO2 sensor is connected, but the finger moves away from the sensor, the oximeter will automatically enter the standby mode. Under this mode, when the SpO2 sensor is connected and a finger is inserted into the sensor, the oximeter will automatically resume the operation mode. Otherwise the oximeter will automatically shut down in 3 minutes.

5.2 Monitoring Screen Display and Operation

5.2.1 Parameter Screen Display

The screen will displays the monitoring parameters when the oximeter is turned on.

If the SpO2 sensor and temperature sensor is connected to monitor a patient's SpO2, the LCD screen displays the measurements of SpO2, PR, bargraph, plethysmogram, body temperature and system information, as shown in figure 5-1.

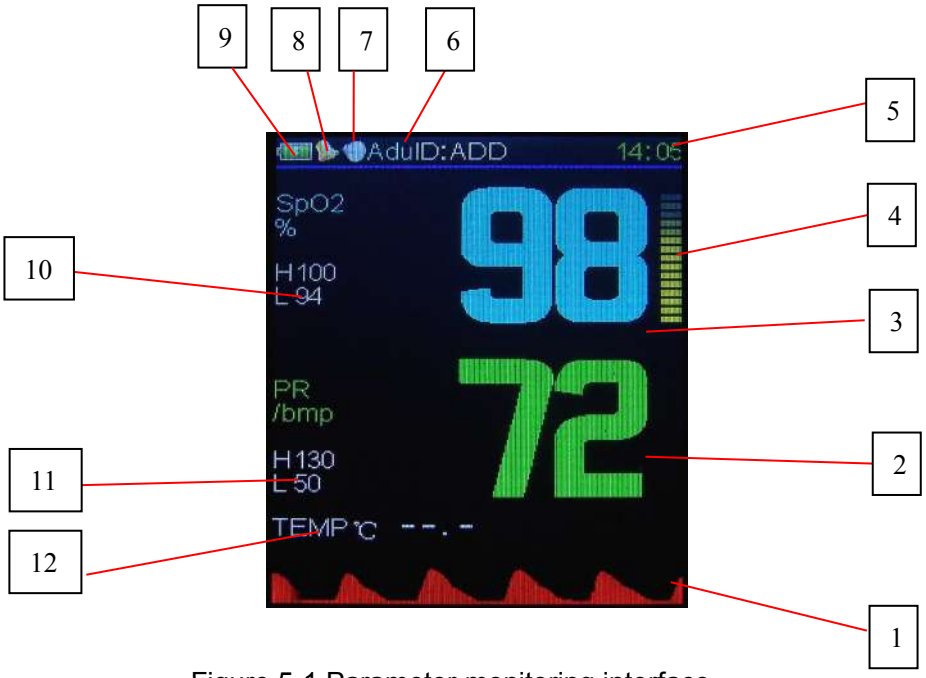


Figure 5-1 Parameter monitoring interface

5.2.2 Description of Displayed Information

Table 5-1 Description of displayed information on the monitoring screen

No.	Description	Remarks
1	Plethysmogram	It displays plethysmogram of pulse rate
2	Pulse rate	It displays PR value and is refreshed every second
3	SpO2	It displays SpO2 value and is refreshed every second
3	Pulse rate	It displays PR value and is refreshed every second
4	Bargraph	If with SpO2 Sensor, it can indicate real-time pulse strength. It shows the pulse rate of patient is weak when the bargraph is lower.。
5	Time	It displays the present time.
6	Patient Type	It displays the patient type (Adu/Neo/Ped)
7	Sound indicator	It displays the situation of sound.
8	Alarm indicator	It displays the situation of Alarm
9	Battery indicator	It displays the battery capacity.
10	SPO2 Alarm limits	Alarm limit value of SPO2， It will alarm if the test result beyond these values.
11	PR Alarm limits	Alarm limit value of PR， It will alarm if the test result beyond these values.
12	Temperature(optional)	It displays body temperature value

5.3 Alarm Monitoring Function

When a parameter's measurement exceeds its alarm limit, the oximeter can give audio and visual

alarms simultaneously. The speaker sounds the alarm and the parameter's measurement flashes on the screen. If the speaker sound is turned off, the parameter's alarm sound will be silenced, but the parameter's measurement still flashes to prompt the alarm.

The alarm sound has top priority when the speaker is not mute. When there is an alarm, the speaker sound the alarm sound but not the pulse sound. Only when there is measurement exceeding its alarm limit, the speaker sounds the pulse sound.

5.4 Parameter setting:

5.4.1 Press the button during the testing situation and it will enter into main menu. The user can use up button & down button to change the setting item. And press the button to enter into the selected submenu.

Figure 5.4.1 main menu

5.4.2 The user can use direction & button to change the setting item in this sound setup submenu, Press the button for parameter setting. Use & button to increase or decrease the value of parameter. Then press button to confirm the parameter setting and return to the submenu. And return the main menu with pressing the exit button.

Figure 5.4.2 Sound setup menu

5.4.3 .The user can use  &  button to change the setting item in this alarm setup submenu, Press the  button for parameter setting. Use  &  button to increase or decrease the value of parameter. Then press  button to confirm the parameter setting and return to the submenu. Finally return the main menu with pressing the  button.

Figure 5.4.3 Alarm setup menu

Note: When you select the different patient type, The alarm limit value will change according to patient type.

5.4.4 The user can use  &  button to change the setting item in this time setup submenu, Press the  button for parameter setting. Use  &  button to increase or decrease the value of parameter. Then press  button to confirm the parameter setting and change to another

parameter. Pressing the button to return the submenu. Finally return the main menu with pressing the button when finishing time setting.

Figure 5.4.4 Time setup menu

5.4.5 The user can use & button to change the setting item in this record setup submenu, Press the button for parameter setting. Use & button to increase or decrease the value of parameter. Then Press button to confirm the parameter setting and return to the submenu. Finally return the main menu with pressing the button.

Figure 5.4.5.1 Record setup menu

If the user selects the new item at the ID submenu, you can see the interface as figure 5.4.5.2. Use & button to move the cursor crosswise, also use button to move the cursor lengthwise. Then press button to confirm the choice of letter. The signal and stand for delete and confirm function. Finally return the main menu with pressing the button.

Figure 5.4.5.2 Record ID input menu

5.4.6 The user can use & button to change the setting item in this system setup submenu, Press the button for parameter setting. Use & button to increase or decrease the value of parameter. Then Press button to confirm the parameter setting and return to the submenu. Finally return the main menu with pressing the button.

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Figure 5.4.6 System setup menu

5.4.7 The user can use & button to change the setting item in this file system setup submenu, Press the button for parameter setting. Use & button to increase or decrease the value of parameter. Then Press button to confirm the parameter setting.

Figure 5.4.7.1 File system setup menu

If the user selects the view item at file submenu, you can see the interface as figure5.4.7.2. Press the button change items among List /Serial No/Page icon. Use & button to select the optional parameter, Then Press button to confirm the parameter setting. Finally return the main menu with pressing the button.

Figure 5.4.7.2 File system View interface

Note:

1. When the record is setting to on situation, the oximeter begins to record the testing result (SpO2&PR), the maximum record will up to 360 hours.
2. The user also can upload the storage data through USB port to the computer, and it also can review the data with software in PC.

Chapter 6. SpO2 Monitoring

6.1 Measurement principle

SpO2 plethysmogram measurement is employed to determine the oxygen saturation of hemoglobin in the arterial blood. The SpO2 parameter can also provide a pulse rate signal and pulse strength.

How the SpO2 parameter works

- SpO2 is a non-invasive measurement of the functional oxygen saturation.
- Arterial oxygen saturation is measured by a method called pulse oximetery. It is a continuous, non-invasive method based on the different spectra absorption of hemoglobin and oxyhemoglobin (called spectrophotometer principle). It measures how much light, sent from light sources on one side of the sensor, is transmitted through patient tissue (such as a finger or a toe), to a receiver on the other side.
- The sensor measurement wavelengths are nominally 660nm for the red LED and 940nm for infrared LED. Maximum optical power output for LED is 4mw.
- The amount of light transmitted depends on many factors, most of which are constant. However, one of these factors, the blood flow in the arteries, varies with time, because it is pulsating. By measuring the light absorption during a pulsation, it is possible to derive the oxygen saturation of the arterial blood. Detecting the pulsation gives a PLETH waveform, pulse rate signal and pulse strength.
- The SpO2 value, PR value, pulse strength and the PLETH waveform can be displayed on the main screen.

6.2 Measurement Steps

Sensor selection for SpO2 measurement depends on the patient's age. For an adult patient, you can choose an adult finger sensor; for a child patient, you can choose a child hand or toe sensor. The finger SpO2 sensor is a finger clip consisting of two parts. The LEDs are placed in one part and the photodetector is placed in another part.

Please follow the steps and figure 6-1 below to use the adult finger SpO2 sensor:

- Insert the sensor's connector to the Oximeter's SpO2 socket.
- Turn on the monition. The LCD screen will display the parameter monitoring screen.
- Attach the sensor to an appropriate site of the patient's finger.
- The readings will be displayed on the LED screen a moment later.

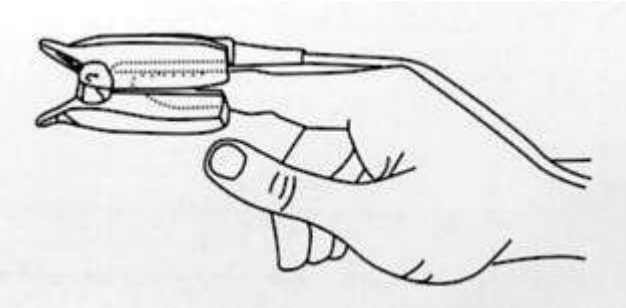

Figure 6-1 Placing the Adult SpO2 Sensor

NOTE

- Make sure to place the SpO2 sensor oh the finger in a correct direction. The LED part of the sensor should be at the backside of the patient hand and the photodetector part at the inside. Make sure to insert the finger to a suitable depth into the sensor so that the fingernail is just opposite to the light emitted from the sensor.
- To acquire accurate results, please read data until the sensor is steadily placed.
- Readings may not be accurate when either the sensor or the patient is moving.

6.3 Measurement Limitations

If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs by an alternate method. Then check the instrument for proper function.

Inaccurate measurements may be caused by:

- Incorrect sensor application or use;
- High-frequency electrical noise, such as noise from electrosurgical apparatus connected to the system;
- Significant levels of dysfunctional hemoglobins (e.g.,carboxyhemoglobin or methemoglobin);
- Significant concentrations of dysfunctional hemoglobin, such as carboxyhemoglobin and methemoglobin;
- Intravascular dyes such as indocyanine green or methylene blue;
- Exposure to excessive illumination, such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight (exposure to excessive illumination can be corrected by covering the sensor with a dark material);
- Excessive patient motion;
- Venous pulsations;
- SpO2 is too low;
- Improper sensor installation or incorrect contact position of the patient;
- Placement of a sensor on the same extremity with a blood pressure cuff, arterial catheter, or intravascular line.
- Polluted fingernail or fingernail polish or artificial fingernail.

Loss of pulse signal can occur in the following situation:

- The sensor is too tight;
- There is excessive illumination from light sources such as a surgical lamp, a bilirubin lamp, or sunlight;

- A blood pressure cuff is inflated on the same extremity as the one with a SpO2 sensor attached;
- The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia;
- There is arterial occlusion proximal to the sensor;
- The patient is in cardiac arrest or in shock.

6.4 Precautions

NOTE

- Do not perform SpO2 monitoring and NIBP measurements on the same arm simultaneously. Obstruction of blood flow during NIBP measurements may adversely affect the reading of the SpO2 value.

WARNING

- Check if the sensor cable is in normal condition before monitoring. Do not use the SpO2 sensor once the package or the sensor is found damaged.
- Remove the SpO2 sensor from the patient after measurement.
- As with any medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation. Cables of electrical surgical equipment should not be winded around that of the SpO2 sensor.
- Do not put the sensor on extremities with arterial catheter or venous syringe.
- If no pulse is found or the reading is unreasonable, first check the patient's condition, and then check the sensor installation and connection with the oximeter, finally ask the qualified engineer to check the device and the SpO2 sensor for proper functions.
- Don't use the oximeter to measure patients whose pulse rate is lower than 30 bpm, which may cause incorrect results.
- Prolonged and continuous monitoring may increase jeopardy of unexpected change of dermal condition such as abnormal sensitivity, rubescence, vesicle, repressive putrescence, and so on. It is especially important to check more frequently the sensor placement of child and patient of poor perfusion or immature dermographia by light collimation and proper attaching strictly according to changes of the skin. Check per 2-3 hours the sensor placement and move it when the skin deteriorates.
- Make sure no contamination or scar exists in the site where the sensor is placed. Otherwise, the measured result may be incorrect because the signal received by the sensor is affected.
- Please use the SpO2 sensor supplied by the Oximeter.
- When used on different patients, the Oximeter is prone to crossed contamination, which should be prevented and controlled by the user. Disinfection is recommended before using the SpO2 sensor on other patients.

CAUTION

- SpO2 sensors are precision and fragile. Avoid pressure and knock. Hold the probe and cable carefully and lightly. If not use it, you should coil up the probe and cable into a loose circle. If the wire inside the cable is tensely pulled, it may cause mechanical damage to the probe and cable.

Chapter 7. Temperature Monitoring (Optional)

7.1 Measurement Steps

You can plug the probe directly into the monitor with a reusable TEMP probe and apply the TEMP probe securely to the patient. Then switch on the machine and make testament.

WARNING: Verify probe cables fault detection before beginning of monitoring phase. Unplug the temperature probe cable from the socket, the screen will display the error message “TEMP SENSOR OFF” and the audible alarm is activated.

WARNING: The calibration of the temperature measurement is necessary for every two years (or as frequently as dictated by your Hospital Procedures Policy). When you need calibrate the temperature measurement, contact the manufacture please.

Chapter 8. Data Transfer Procedure

Connecting the USB line from the machine to the computer after switching off the pulse oximeter. It will enter into transfer mode after switching on the machine again. The signal of USB will show in the LCD display, but not measure the data. It will transfer the data from pulse oximeter to the computer through the USB data line. As shown in figure 8-1.

The computer will indicate the information of finding a new disk driver. Then you can find a file named oxmieter.bin in the removable disk. You can use software oximeter-viewer in the CD to view the measured result at your computer.

Figure 8-1 Data Transfer Interface

Chapter 9. Maintenance

9.1 System Check

9.1.1 Check before Using

Before using the oximeter, perform the following steps:

- Check if there is any mechanical damage;
- Check if all the outer cables and accessories are in good condition;
- Check if all the monitoring functions of the oximeter can work normally so as to make sure that the oximeter is in proper working condition.

In case of any damage, abnormal function, hidden safety danger or exception, do not use the device on patient, contact the technician in your hospital or the manufacture immediately.

> Notes: The TEMP probe should not be heated above 100℃ (212℉). It should only be subjected briefly to temperatures between 80℃ (176℉) and 100℃ (212℉).

9.1.2 Routine Check

Make sure the qualified service personnel have implemented a complete inspection, including the functional safety check, after the oximeter has been used for 6-12 consecutive months, or after oximeter servicing or system upgrading. This is to ensure the normal operation of the system.

Store the device without battery if unused for a long time. Otherwise the battery may be damaged because of being thoroughly exhausted.

WARNING

- Failure on the part of the responsible hospital or institution employing the use of the monitoring equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazard.
- The safety inspection or maintenance, which requires opening the oximeter housing, must be performed by trained and authorized personnel only. Otherwise. Equipment failure and possible health hazard may be caused.

9.2 General Cleaning

Your equipment should be cleaned on a regular basis. When it is polluted by dust, oil, sweat or blood etc, it should be cleaned at once. If there is heavy pollution or lots of dust and sand in your place, the equipment should be cleaned more frequently. Before cleaning the equipment, consult your hospital's regulations for cleaning, disinfecting and sterilizing equipment.

The exterior surfaces of the equipment may be cleaned gently with a clean and soft cloth, sponge or cotton swap, dampened with a non-erosive cleaning solution. Drying off excess cleaning solution before cleaning the equipment is recommended.

WARNING

1. Power off the oximeter and stop charging the battery before cleaning.
2. The surface temperature probes should be used.
3. The temperature probe must not be sterilized in steam.

Following are examples of cleaning solutions:

- Diluted soap water
- Diluted formaldehyde (35%-37%)
- Diluted ammonia water
- Hydrogen peroxide(3%)
- Alcohol
- Ethanol(70%)
- Isopropanol (70%)
- Diluted sodium hypochlorite solution(bleaching agent)

NOTE

- Sodium hypochlorite solution with a concentration of 500ppm (1:100diluted bleacher solution used in family) -5000ppm (1:10diluted bleacher solution used in family) is very effective. How much ppm depends on how much organic matter (blood, propagation grume etc.)Existing on the surface.

CAUTION

- NEVER use strong solvent, such as acetone.
- ALWAYS dilute the solutions according to the manufacturer's suggestions.
- NEVER use abrasive, erosive cleaners, or cleaners containing acetone
- NEVER permit fluids run into the casing, switches, connectors, or any ventilation openings in the equipment.
- NEVER submerge the equipment into water or any cleaning solution, or pour or spray water or any cleaning solution on the equipment.
- ALWAYS wipe off all the cleaning solution with a dry cloth after cleaning and dry the Oximeter in the air. Never dry the Oximeter in violent sunshine or toast it under high temperature.
- If the Oximeter is polluted by chemical substance, the users should handle it effectively according to the properties of the chemical substance.

The probes and cables may be cleaned with a clean and soft cloth, sponge or cotton swap, dampened with ethanol.

WARNING

- The cleaning solutions above can only be used for general cleaning. If you use them to control infections, the manufacturer shall assume no responsible for the effectiveness. Please consult your hospital's infection controllers or professionals.

9.3 Disinfection

Disinfection may cause damage to the equipment. We recommend the disinfection is contained in the hospital's servicing schedule only when necessary. The equipment should be cleaned prior to disinfection.

Recommended disinfection material: alcohol based (Ethanol 70%,Isopropanol 70%), and aldehyde based.

The probe cables may be disinfected with hydrogen peroxide (3%) or isopropanol (70%). Active reagents are also effective. The connecters cannot be submerged into the above solutions.

NOTE

- ALWAYS dilute the solutions according to the manufacturer's suggestions and adopt lower concentration if possible.
- NEVER submerge the equipment into water or any solution, or pour water or any solution on the equipment.
- ALWAYS wipe off all the excess liquids on the equipment surface and accessory surface with a dry cloth.
- NEVER use ETO and formaldehyde to disinfect.
- NEVER permit high-pressure and high-temperature disinfection of the equipment and accessories.

WARNING

- Disinfection may cause damage to the equipment; therefore, when preparing to disinfect equipment, consult your hospital's infection controllers or professionals.

9.4 Disposal

To avoid contaminating or infecting personnel, the environment or other equipment, make sure you disinfect or decontaminate the device appropriately before disposing of it in accordance with your country's law for equipment containing electrical and electronic parts.

Chapter 10. Accessories

Standard Accessory	
Handheld Pulse Oximeter unit	1pcs
Adult Clip SpO2 Sensor	1pcs
USB Cable	1pcs
CD Software (User Manua,PC software)	1pcs
Optional accessory	
Adult Soft tip SpO2 sensor	1pcs
Child finger clip SpO2 sensor	1pcs
Child soft tip SpO2 sensor	1pcs
Neonate Wrap SpO2 sensor	1pcs
Skin Surface Temperature Probe	1pcs

CAUTION

- Using other accessories may cause damage to the device.

SpO2 sensor

This Module connect to the oximeter sensor with a analogous PD. and the LED wavelenth is 660nm Red light or 905nm infrared light.
This module can be compatible with Nellcor Spo2 Sensor.

Order

Model No.	Description
S901/S901B	Adult finger clip SpO2 sensor
S902	Adult Soft tip SpO2 sensor
S903	Child finger clip SpO2 sensor
S904	Child soft tip SpO2 sensor
S905	Neonate Wrap SpO2 sensor
T501	Skin Surface Temperature Probe

Chapter 11. Appendix a Specifications

General

Monitoring Parameters: SpO2\PR\Body temperature (Optional)

Signal sockets: SpO2 socket\USB socket\ Temperature sensor socket.
Display screen
Type: 2.8 inch TFT LCD
Display area: 58mm×43mm
Size
142mm (L) x78mm (w) x28mm (H)
Weight
250g (not include probes and battery)

Electrical specifications

Working voltage: DC4.0V-6.0V or 3.5V-4.2V Li battery.

Internal battery: 4 AAA alkaline battery or 1800MAH rechargeable Li battery

Run time: 15-hour continuous operation with a new, fully charged battery (environment temperature is 25℃)
Power Consumption: Smaller than 80mA(Normal)

Environment

Temperature

Operation: 5℃-40℃; Transportation and storage: -20℃-55℃

Humidity

Operation: 15%-85%(no condensing); Transportation and storage: 10%-95%(no condensing)

Altitude

Operation: 70KPa-106 KPa; Transportation and storage: 50KPa-106 KPa

Parameter Specifications

SpO2

Patient: adult, child

Range: 35%-100%

Resolution:1 %

Accuracy: (70%-100%)

2% Normal

3% Motion or low perfusion

Below 70% Not specified

PR

Range: 25bpm-250bpm

Resolution: 1bpm

Accuracy: (25～250BPM)

2bpm Normal

3bpm Motion or low perfusion

Temperature

Channel	1
Measuring and Alarm Range	18 ~ 45 °C
Resolution	0.1°C
Accuracy	0.1°C
Actualization interval	about 1 Sec.
Average Time Constant	< 10 Sec.