

**USER GUIDE** 

USES BAYER'S CONTOUR® BLOOD GLUCOSE TEST STRIPS

#### Indications for Use:

The CONTOUR® LINK Wireless Blood Glucose Monitoring System is an over the counter (OTC) device utilized by persons with diabetes in home settings for the measurement of glucose in whole blood, and is for single-patient use only and should not be shared. The CONTOUR LINK Wireless Blood Glucose Monitoring System is indicated for use with fresh capillary whole blood samples drawn from the fingertip only.

CONTOUR test strips are intended for self-testing by persons with diabetes for the quantitative measurement of glucose in whole blood samples from 20 to 600 mg/dL.

The CONTOUR® LINK Wireless Blood Glucose Monitoring System is intended to be used to transmit glucose values to Medtronic MiniMed Paradigm® Insulin Pumps or Medtronic MiniMed Paradigm® REAL-Time Revel™ Insulin Pumps through use of radio frequency communication.

The CONTOUR LINK Wireless Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

#### **Important Safety Instructions**

The *MICROLET*<sup>®</sup>2 lancing device included in this kit is not intended for use on multiple patients by health care professionals.

Neither the *CONTOUR® LINK* meter nor the *MICROLET®2* lancing device or lancets should be used with more than one person due to the risk of infection. The meter and lancing device are for single patient use. Do not share them with anyone including other family members. Do not use on multiple patients.

After first use, all parts of the *CONTOUR® LINK* kit are considered contaminated with body fluids (blood) and could potentially transmit infectious diseases, even after you have performed the recommended cleaning and disinfection process.

Used test strips and lancets are possible biohazards and must be disposed of properly.

Read your *CONTOUR® LINK* user guide, the *MICROLET®2* lancing device insert and all instructional materials provided in your meter kit before testing. Please follow all instructions for use and care exactly as described to help avoid inaccurate results.

Always wash your hands well with soap and water before and after handling the meter, lancing device, or test strips.

#### WARNING:

- The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!<sup>1,2</sup>
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

For complete instructions on cleaning and disinfecting your meter and lancing device, please see page 16.

IMPORTANT: Examine product for missing, damaged, or broken parts. If the test strip bottle is open inside a new box of strips, do not use those strips. Contact Bayer Diabetes Care Customer Service at 1-800-348-8100 (available 24 hours a day, 7 days a week) for replacement parts.

For more information see:

"FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ ucm224025.htm

"CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010)

http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

Important Safety Instructions

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# Important Federal Communications Commission (FCC) Information

# When the *Send* option on the *CONTOUR® LINK* meter is set to ON:

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: 1. This device may not cause harmful interference, and

2. This device must accept any interference received, including interference that may cause undesired operation.

Warning: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This portable transmitter with its antenna complies with FCC / IC RF exposure limits for general population / uncontrolled exposure.

# **FCC Statement**

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- If you need help, please contact the Bayer Diabetes Care Customer Service at 1-800-348-8100 (available 24 hours a day, 7 days a week).

#### Need Help? Bayer Diabetes Care: 1-800-348-8100 (available 24 hours a day, 7 days a week)

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Important

Your Testing Tools

Thank you for choosing Bayer's CONTOUR® LINK wireless blood glucose monitoring system! We are proud to be your partner in helping you manage your diabetes. The CONTOUR® LINK meter does much more than test your blood glucose — it automatically sends your blood glucose result to compatible\* designated Medtronic partner devices using a wireless, radio frequency transmission.

#### Your CONTOUR® LINK Meter:



\* For information on compatible Medtronic devices, contact Medtronic Customer Service at 1-800-646-4633.

#### Additional Materials

- **CONTOUR®** Test Strips—Use for blood glucose or control solution testing. Supplied in a handy bottle with an easy-toopen flip-top lid.
- MICROLET<sup>®</sup>2 Lancing Device—Use for fingertip puncture with Baver's MICROLET lancet.
- BATTERIES—Use two 3-volt (DL2032 or CR2032) lithium batteries. Replace when necessary.

#### Your Meter Display

The picture below shows all the symbols that will appear on your meter display. When the meter is off, press and continue holding the  $\blacktriangle$  or  $\blacktriangledown$ button. All segments will be displayed and remain on while holding the button down for 10 seconds. Repeat as needed to compare your meter to the display shown below.

While all characters are displayed, it is most important to verify that **B B** is fully displayed. If it is not, see Error Codes and Symbols (page 37). This may affect the way you see your results.

Top area on the display presenting	Indicates Send option is turned on.
date and time.	88/881488188 RM
Indicates an alarm has been set.	Image: Constraint of the second s
Pre-meal result marker.	<b>8.8.8</b> Center area on the display that shows either your test result or any error codes.
Post-meal	Control result marker.

Indicates the meter is ready to test.



Indicates it is too cold a test result or too hot for your as unique or different. meter to test accurately. **BM** or **PM** will appear if

the meter is in 12 hour setup.

d.m/d Displays the date format

mmo 7dL

Results are displayed along with the preset units of measure. The 7 appears when viewing the number of results over the past 7 days.

Α Average.



Indicates the batteries are low and need to be changed.

2

# **Your Meter Features**

**Programmed:** Your *CONTOUR® LINK* meter has been preset at the factory with the standard date and time. To change these settings or to use advanced meter features, such as meal markers, read through the Options section of your User Guide.

**Easy:** The *CONTOUR LINK* blood glucose monitoring system is all about simplicity. You will notice its uncomplicated approach the first time you see it. Simple things like the use of three large buttons and a clear display are sure to make this your favorite meter right from the start.

**Automatic:** You no longer have to worry about **coding** your meter or marking a control test result. The *CONTOUR LINK* meter does it automatically. It will even tell you when a test strip is under-filled.

**Makes Sense:** You will find features asked for by customers *just like you*. Practical features like a **fast** test time, a very **small** blood sample size, and a simple testing procedure (*No Coding*<sup>TM</sup> *technology*!) make the *CONTOUR LINK* meter *your* meter.

**Convenient:** Your *CONTOUR LINK* meter takes up about as much room in your pocket or bag as your key ring. The meter's small size, sleek design, and ease of use allow you to take it everywhere. You will be likely to test more often, which can mean better control of your diabetes.

**"Talks" to Your Compatible Medtronic Device:** Your *CONTOUR LINK* meter has the ability to automatically send your glucose result directly to your compatible Medtronic MiniMed Paradigm<sup>®</sup> Insulin Pump or Medtronic MiniMed Paradigm<sup>®</sup> REAL-Time Revel<sup>™</sup> Insulin Pump. This eliminates the need to manually enter your blood glucose result into the insulin pump's Bolus Wizard<sup>®</sup> Calculator, which calculates an estimated bolus to support your food intake or to correct a high blood glucose. Your *CONTOUR LINK* meter can also send your fingertip blood glucose result directly to your compatible MiniMed Paradigm<sup>®</sup> REAL-Time Revel<sup>™</sup> System, eliminating the need to manually enter the result when calibrating the system.

# Important Things to Know

Your CONTOUR® LINK blood glucose meter is specific for glucose and has been referenced to plasma/serum values. Methods calibrated to plasma/serum can be 9% to 15% higher than the results of whole blood glucose assay methods.

Always keep the test strips in the original bottle. Tightly close the bottle immediately after removing a test strip. The bottle is specially designed to provide a dry environment for the test strips. Extended exposure to room humidity from leaving the bottle open or not storing the test strips in the original bottle will damage your test strips.

- Avoid excessive "milking" of your finger when forming a drop of blood and test immediately after forming the blood drop.
- DO NOT use a test strip that appears damaged or has been used. Test strips are for single use only.

**IMPORTANT NOTE:** Your meter has been preset and locked to display results in mg/dL (milligrams of glucose per deciliter). Test results in mg/dL will **never** have a decimal point. In some countries, the meters are preset to display units in mmol/L (millimoles of glucose per liter). Results in mmol/L will **always** have a decimal point. Check your display to ensure that results are being displayed in the expected units; if they are not, contact Bayer Diabetes Care Customer Service at 1-800-348-8100 (available 24 hours a day, 7 days a week).

# Example:

# $95\frac{mg}{dL}$ or $5.3\frac{mmol}{L}$

IMPORTANT: When a low battery warning displays on the meter, replace the battery as soon as possible to avoid a test result not being stored in the meter memory. **Talking to Your Compatible Medtronic Device** 

# First Things First: Talking to Your Compatible Medtronic Device

Your *CONTOUR® LINK* meter is already set with the *Send* option turned on. (To turn the option off, see page 24.) Every time the meter displays a new blood glucose test result, the result is automatically sent to your compatible Medtronic device. However, your Medtronic device will only accept the glucose result if the Meter Option in your device's Utilities Menu is set to **On** and you have programmed the device with the meter's ID (serial) number. Up to three different meter ID numbers, can be accepted. See your Medtronic device addendum that is included in your device box.

- 1. Program your meter ID number into your compatible Medtronic device. The ID number is the serial number found on the left side of the back label of your meter. It is a 6-digit numeric or alphanumeric number (0–9, A–F); for example, 120462 or B12B3C. See the User Guide for your Medtronic device for complete information on this step.
- **2.** Set your meter to the same time and date as your Medtronic device (see page 25 in this User Guide).

The Medtronic device can receive a glucose result only if you have entered your meter's ID number into the device. Conversely, no one else's insulin pump can receive your glucose result, unless your meter ID number has been entered into that device. The meter uses a wireless signal to send the blood glucose result to the Medtronic device. However, the *Send* option must be set to ON (see page 24) and the meter and Medtronic device must be within 4 feet of each other. If you are not using the link functionality on your Medtronic device, you may want to turn the *Send* option off to save battery power.

# **Before You Begin**

- 1. Have all the materials you will need ready before you begin testing. This includes your *CONTOUR® LINK* meter, the *CONTOUR®* test strips, and the *MICROLET®*2 lancing device with *MICROLET®* lancets. You may also need *CONTOUR* control solution to run a quality control check.
- **2.** Read your User Guide and all instructional materials provided in your meter kit before testing.
- **3.** Let the meter and test strips adjust to the temperature of the location where you are testing. Whenever the meter is moved from one location to another, allow 20 minutes for the meter to adjust to the temperature of that new location before performing a blood glucose test.
- 4. It is important not to use the test strips or control solution if the expiration date printed on the bottle label and carton has passed or if it has been six months (180 days) since you first opened the control solution bottle. It will help to write the six month *discard date* on the label in the area provided when you first open the control solution.
- 5. Before testing, always wash your hands with warm soapy water and dry them well.

#### WARNING:

- The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!<sup>1, 2</sup>
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

For complete instructions on cleaning and disinfecting your meter and lancing device, please see page 16.

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## **Getting Ready to Test:**

Read the insert for the MICROLET®2 lancing device for complete instructions.

Before testing, always wash your hands with warm soapy water and dry them well.



Remove the endcap from the MICROLET 2 lancing device.

Rotate (do not remove) the protective cap on a lancet ¼ turn.

Insert the lancet firmly until it comes to a full stop. This will "cock" the device.

NOTE: You can also pull and release the cocking end to "cock" the device.

Twist off the lancet cap. Be sure to save it for disposing of the used lancet

Replace the device endcap.

Remove a test strip from the bottle. Tightly close the bottle lid immediately after vou have removed the test strip.



**NOTE:** Check the expiration date. Make sure the test strip does not appear torn or damaged.

Tightly close the bottle lid immediately after you have removed the test strip. Excess moisture could damage the test strip.



Hold the test strip with the gray end facing up.

Insert the gray end into the test strip port on the meter. No need to enter a code!

Check battery status. If battery shows low, see page 41.



The meter will turn on. A test strip with a flashing blood drop will appear, letting you know the meter is ready to test, and the Send arrow () will show that the meter is set to send the result to your compatible Medtronic device

**Getting Ready to Test** 

Testing

Need Help? Bayer Diabetes Care: 1-800-348-8100 (available 24 hours a day, 7 days a week)

# Testing

# Getting the Blood Drop:



## Fingertip Testing —

The depth of the puncture depends upon the adjustable endcap setting you choose and the amount of pressure applied to the puncture site. You should determine which combination works best.

# **Testing Your Blood:**

Immediately touch the **tip** of the test strip to the drop of blood. The blood is pulled into the test strip through the tip.



Press the endcap firmly against the puncture site and press the blue release button.

Wait a few seconds. Stroke your hand and finger towards the puncture site to form a drop of blood. Do not squeeze around the puncture site.

Test immediately after you have formed a blood drop.

# Do not press the tip against the skin or place the blood on top of the test strip.

Hold the tip of the test strip in the blood drop until the meter beeps.

After the beep, you will see the meter count down the five seconds until the test is complete and your result is displayed.

#### WARNING:

- The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!<sup>1, 2</sup>
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection. For complete instructions on cleaning and disinfecting your meter and lancing device, please see page 16.

Testing



Your test result will begin flashing to indicate that it is being sent to your Medtronic device. It will continue to flash for at least 5 seconds (up to 60 seconds). until the

meter receives a message from the Medtronic device that the result has been received. If your result does not flash, check to be sure the *Send* option is turned on (see page 24).

The test result will also be automatically stored in the meter memory.

If you have set your meter to use the special marker options (see page 28), the markers must be selected while the result is still being displayed, **before** removing the strip or turning the meter off.

#### NOTES:

- 1. A result of "LO" or "HI" will not be sent to the Medtronic device, even when the *Send* option is on. Results of 10-19 mg/dL will be sent to the Medtronic device; however the device will ignore these results (they will not be displayed).
- 2. **Important:** Always check the display on your Medtronic device to ensure that the glucose result shown agrees with the meter display.
- **3.** Do not attempt to insert a new test strip until the display stops flashing. Doing so will cause the transmission to be stopped.

Need Help? Bayer Diabetes Care: 1-800-348-8100 (available 24 hours a day, 7 days a week)

#### Stopping a Result While it is Being Sent

If you want to stop the transmission of a result (if it has not been accepted by the Medtronic device in 5 seconds), press  $\mathbf{M}$ . The transmission will be cancelled. Be aware that the result **cannot** be resent later.

#### Turning off the Send option for a Single Test Result

If you do NOT want to send a blood test result to your Medtronic device, you can turn off the *Send* option for a single test. You may want to do this if you do not want to create a wireless signal (for example, if you have been asked to turn off all electronic devices on an aircraft).

- Insert a test strip into the meter to turn the meter on. Before you begin your test, press and hold the ▲ or ▼ key until "UFF" is displayed. The ↑ displayed next to the date will disappear, indicating that the Send option is temporarily turned off.
- Test your blood as usual. The result will not flash, indicating that it is not being sent.
- 3. When you turn the meter on to perform another test, the *Send* option will again be on (the ↑ will be displayed).





## Test results

**Expected Values:** Blood sugar values will varv depending on food intake, medication dosages, health, stress, or activity. Non diabetic expected values are 75 to 110 mg/dL fasting.<sup>3</sup> You should consult with your health care professional for glucose values specific to vour needs.

#### WARNING:

- Test your blood again if your test result is below 50 mg/dL, above 250 mg/dL, or if you see "LO" or "HI" on the meter display. If your glucose level is still below 50 mg/dL, above 250 mg/dL, or shows as "LO" or "HI", call your physician or health care professional immediately.
- Do not change your medication based on CONTOUR® LINK blood glucose results without the advice of your physician or health care professional.



To turn your meter off. simply remove the test strip. Carefully dispose of the used test strip in an appropriate waste container (The meter will automatically turn off after three minutes if you do not remove the test strip.)

**NOTE:** If the glucose result is still being sent to your Medtronic device, the meter will not turn off until the transmission is complete.

Need Help? Bayer Diabetes Care: 1-800-348-8100 (available 24 hours a day, 7 days a week)

#### Removing the used lancet:

In one hand, hold the lancing device with your thumb on the grip indent, with your other hand, hold the gray endcap dial as shown, and gently snap off the endcap.



Place the round protective lancet cap on a flat surface with the Bayer logo facing down.

With the used lancet still in the lancing device, push the lancet needle completely into the middle of the exposed side of the cap.

While (a) pressing the blue release button. (**b**) pull the blue cocking handle, and the lancet will drop into the container you have selected

Dispose of the used lancet carefully to prevent injury or contamination to others

Do not reuse lancets. Use a new MICROLET<sup>®</sup> lancet each time you test

IMPORTANT: Always wash your hands well with soap and water before and after handling the meter, lancing device or test strips.



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Testing

# Testing

## **Cleaning and Disinfection**

Your *CONTOUR® LINK* system should be cleaned and disinfected once a week. Use **only** Clorox® Germicidal Wipes containing 0.55% sodium hypochlorite (bleach), which has been proven to be safe to use with the *CONTOUR® LINK* meter and *MICROLET®2* lancing device.

**Cleaning** is the removal of visible dirt and debris, but does not reduce the risk for transmission of infectious diseases. Your *CONTOUR® LINK* wireless blood glucose monitoring system should be cleaned of dirt and debris once a week.

**Disinfecting** (if performed properly) reduces the risk of transmitting infectious diseases. Your meter and lancing device should be disinfected once a week.

#### WARNING:

• Always wash your hands well with soap and water before and after testing and handling the meter, lancing device, or test strips.

**NOTE:** If your meter is being operated by a second person who is providing testing assistance to you, the meter and lancing device should be disinfected prior to use by the second person.

The cleaning and disinfecting directions provided will not cause any damage or degradation to the external case, buttons or display.

Your *CONTOUR LINK* meter and *MICROLET 2* lancing device have been tested for 260 cycles of cleaning and disinfection (one cycle per week for 5 years). These devices have been demonstrated to withstand 5 years of cleaning and disinfection without damage. You should call Bayer Diabetes Care Customer Service for assistance if your device malfunctions for any cause or if you notice any changes in the meter case or display. Clorox<sup>®</sup> Germicidal Wipes are available for purchase online at http://www.officedepot.com or http://www.amazon.com or for more information call Bayer Diabetes Care Customer Service at **1-800-348-8100** (available 24 hours a day, 7 days a week).

For more information see:

"FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) http://www.fda.gov/MedicalDevices/Safety/ AlertsandNotices/ucm224025.htm

"CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010)

http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

## **Cleaning Your Meter**

Supplies Needed for Cleaning:

- Clorox<sup>®</sup> Germicidal Wipes containing 0.55% sodium hypochlorite (bleach)
- Paper towels
- 1. Carefully clean the meter with Clorox® Germicidal Wipes until all soil is removed. *Do not allow cleaning solution to run into the meter through areas such as around the buttons or the meter's test strip or data ports.*
- 2. Dry as necessary with a clean paper towel.

# **Disinfecting Your Meter**

Supplies Needed for Disinfecting:

- Clorox<sup>®</sup> Germicidal Wipes containing 0.55% sodium hypochlorite (bleach)
- Paper towels
- Timing device
- **1.** Before disinfecting, clean the meter as described above in CLEANING YOUR METER.

Testing

**Cleaning and Disinfection** 

# FOR PROPER DISINFECTION, YOU MUST KEEP ALL METER SURFACES WET FOR 60 SECONDS.

Using a new Clorox<sup>®</sup> Germicidal Wipe, carefully wipe all outer surfaces of your meter until wet. *Do not allow cleaning solution to run into the meter through areas such as around the buttons or the meter's test strip or data ports.* 





**2.** Dry all meter surfaces and test strip port using a clean paper towel if needed.

# **Cleaning Your Lancing Device**

Supplies Needed for Cleaning:

- Clorox<sup>®</sup> Germicidal Wipes containing 0.55% sodium hypochlorite (bleach)
- Paper towels
- **1.** Clean the *MICROLET*<sup>®</sup>2 lancing device with Clorox<sup>®</sup> Germicidal Wipes until all soil is removed.
- 2. Dry as necessary with a clean paper towel.

# **Disinfecting Your Lancing Device**

Supplies Needed for Disinfecting:

- Clorox<sup>®</sup> Germicidal Wipes containing 0.55% sodium hypochlorite (bleach)
- Paper towels
- Timing device
- **1.** Before disinfecting, clean the lancing device as described above in CLEANING YOUR LANCING DEVICE.
- 2. Remove the endcap and lancet, if present.



Testing

**Disinfecting Your Meter** 

# FOR PROPER DISINFECTION, YOU MUST KEEP ALL ENDCAP SURFACES WET FOR 60 SECONDS.

**3.** Using a new Clorox<sup>®</sup> Germicidal Wipe, carefully wipe all external and internal surfaces of the endcap until wet.



# FOR PROPER DISINFECTION, YOU MUST KEEP ALL LANCING DEVICE SURFACES WET FOR 60 SECONDS.

**4.** Use Clorox<sup>®</sup> Germicidal Wipes to disinfect all exposed surfaces of your lancing device until wet.



**5.** Dry all lancing device surfaces and endcap with a clean paper towel if needed.

# **Control Solution Testing:**

Use only Bayer's CONTOUR® control solutions (Normal, Low, or High) with your CONTOUR meter. Using anything other than CONTOUR control solution could present incorrect results.

## Run a control test:

- When using your meter for the first time;
- When you open a new vial of test strips;
- If you think your meter may not be working properly; or
- If you have repeated unexpected blood glucose results.

Remove a test strip from the bottle.

Tightly close the bottle lid immediately after you have removed the test strip. Excess moisture could damage the test strip.

**NOTE:** Check the expiration and discard date. Make sure the test strip does not appear torn or damaged.

Hold the test strip with the gray end facing up.

Insert the gray end into the test strip port on the meter.



Testing

**Disinfecting Your Lancing Device** 

Testing

The meter will turn on. A test strip with a flashing blood drop will appear, letting you know the meter is ready to test.



Gently rock the control bottle before opening to ensure it is mixed well. Squeeze a small drop of control solution on a clean nonabsorbent surface (such as a piece of wax paper). **Do not apply the control solution to your finger nor directly to the test strip from the bottle.** Recap the **bottle immediately.** 

Immediately touch the **tip** of the test strip to the drop of control solution. The solution is pulled into the test strip through the tip.

Hold the test strip in the drop until the meter beeps.

After the beep, you will see the meter count down five seconds until the test is complete and your control test result is displayed.





The meter will automatically recognize and mark ( $\checkmark$ ) the control result for you.

NOTE: The  $\checkmark$  does not indicate the control test result is within the specified range.

Compare your control test result with the Normal Control Range printed on the test strip bottle label or on the bottom of the test strip box.

NOTE: Low and High control range values can be found on the bottom of the test strip box.

If your control test result is out of range, do not use your meter for blood glucose testing until you resolve the issue. See "What You Should Do" on page 38.

To turn your meter off, simply remove the test strip. The result will automatically be marked with a  $\checkmark$  and stored in the meter memory. Control results will not be included in your 14 day blood glucose average or in the 7 day total. They are also not sent to your Medtronic device (the result does not flash). 95 <del>\*</del>

10/13 12:08 PM

800-348-8100

96-116 mg/

LOT: 1016960

Carefully dispose of the used test strip.

Testing

Need Help? Bayer Diabetes Care: 1-800-348-8100 (available 24 hours a day, 7 days a week)

www.bayerdiabetes.com/us

# Setting Your Options:



Options

Setting the Send Option

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You can set your meter to display different options.

To aet into the Setup mode, press and hold **M** for three seconds A complete display will briefly appear, then the Send option will be displayed.

**NOTE:** You can exit the Setup mode at any time by pressing and holding M for 3 seconds. All selections you have made up to that point will be saved.

# Setting the Send Option:

The Send arrow (1) will be displayed at the top of the display and the word "Un" will be flashing.

This option controls whether you want to send your test results to vour Medtronic device.



Press  $\blacktriangle$  or  $\checkmark$  to choose whether to turn the Send option on or off. (If you are not using the link functionality on your Medtronic device, you may want to turn the Send option off to save battery power.)

Press M to set

# Setting the Time:

Press M to set

Press M to set

The time will now appear on the display. The number in the **hour** position will be flashing. Press **A** or ▼ until you reach the correct time.

The number in the **minute** position will now flash Press  $\blacktriangle$  or  $\checkmark$  until

The **AM** or **PM** will now flash Press  $\blacktriangle$  or  $\checkmark$  to choose AM

you reach the correct minute.



÷∭₽M





Press M to set.

or PM

# Setting the Date:

The date will now appear on the display. The **year** will be flashing. Press  $\blacktriangle$  or  $\blacksquare$  to reach the current year. Press M to set



-2424 20 11

2-24-20 11

The **month** will now flash Press or  $\mathbf{\nabla}$  to reach the current month. Press **M** to set.

The **day** will now flash. Press ▲ or ▼ to set the day.

Press M to set

m/d

m/d

Need Help? Bayer Diabetes Care: 1-800-348-8100 (available 24 hours a day, 7 days a week)

# Setting the Sound:



The flashing bell symbol will now appear on the display, along with the word "un."

This option controls whether you want to hear the "beeps" during testing.



12 X -

24 X-

Press  $\blacktriangle$  or  $\checkmark$  to choose whether to turn the buzzer on or off. (You will hear a beep when you switch to the **Un** screen.)

Press **M** to set.

# Setting the 12 or 24 Hour Clock:

**12H** will now flash on the display. Press ▲ or ▼ to choose the 12H or 24H setting.

This option lets you set the meter to display the time as a 12 hour setting with AM and PM or as a 24 hour display (military time).

Press **M** to set.

# Setting the Month and Day format:

**m/d** will now flash on the display. Press  $\blacktriangle$  or  $\blacktriangledown$  to choose how you want the date to appear (month/ day or day.month).

Press **M** to set.

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— m/d

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# Setting the Markers and Test Reminder Alarm:

You will now see three markers displayed on your meter, along with the word "**DFF**."

Your CONTOUR® LINK meter can give you the option of marking your test results by turning this option on.

# (See pages 28–33 to learn how to use these options!)

Press  $\blacktriangle$  or  $\blacktriangledown$  to turn the marker option on or off.

Press **M** to set.

# Setting the Test Reminder Alarm Time:

You can now select the timing for the alarm to sound. The default setting is 2.0 hours (2.0 H); this can be changed to 1.0, 1.5 or 2.5 hours.

Press  $\blacktriangle$  or  $\blacktriangledown$  to change the alarm time.

Press **M** to set.

You have now completed the setup of your meter!

The final display will remain on for 3 seconds, showing all the options you have chosen.

If you ever want to change the options you have chosen, simply go back to page 24 and follow the Setup instructions.



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Time, Date,

Options

Setting the and Sound

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12:0

Press M or remove the used test strip to automatically save the test result in the meter memory.

# OR

Press  $\blacktriangle$  or  $\checkmark$  until all three markers disappear from the display. Press **M** and remove the used test strip.

Dispose of the used test strip and lancet properly to prevent injury or contamination to others.

### If you want to mark the test result:

Press  $\blacktriangle$  or  $\checkmark$  to move to the marker you want to set. You will know when you have chosen a marker when you see the box around it flashing on the display.



Press M to set

If you mark a result with the 🔴 the (O) will appear with a box flashing around it.

This allows you to set an alarm that will go off in 2 hours (or whatever time you have selected in the Setup mode), to remind you to run a post-meal test.

If you want to set the alarm, press M.

If you do not want to set the alarm, press  $\blacktriangle$  or  $\blacktriangledown$ . The will disappear showing an empty flashing box.

Press M to set

Using the Markers and Test Reminder Alarm:

**Contour LINK** 

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If you have set your meter with the marker option on (see page 27), your meter will display three markers next to vour blood glucose test result. (If the Send option is on. the markers will not be displayed until after the result has been sent to the Medtronic device and the display stops flashing.)

Be sure to leave the used test strip in the meter until you have finished marking the results.

- **Pre-meal** = Marks a test result that was taken before a meal
- **Post-meal** = Marks a test result that was taken after a meal

Logbook = Marks any result as being unique or different in some way and for which you may want to make notes in your Clinilog® logbook. Seeing a result with this symbol next to it in the memory will help remind you that there is more information recorded about this test result

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Using the Markers ar Test Reminder Alarm

Options

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If you do not want to run another test immediately after the alarm sounds, press any button to turn your meter off.

The meter will only set one alarm. It will remember the last alarm set. Any previous alarm setting will be lost.

Press  $\blacktriangle$  or  $\blacktriangledown$ . The empty box (\_\_\_) will now indicate the alarm has been turned off.

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Press **M** to set.

Test Reminder Alarm:

When the alarm sounds, the meter will automatically turn on, the alarm will sound, and the display will show the pre-meal test result you marked when you set the alarm. Pressing any button will silence the alarm.

You can now run another test by placing a test strip in the test strip port and following the testing instructions (page 8).

When you have completed this test and the result is shown on the display, you may want to mark this test with the  $\tilde{\chi}$  symbol to identify this test result as your post-meal result.

**For example:** An alarm has been set. You decide to retest before that alarm goes off. If you mark the new test result with a pre-meal marker ( $\textcircled{\bullet}$ ) and set a new alarm ( $(\textcircled{\bullet})$ ), the old alarm setting will be ignored and only the new setting will sound in 2 hours (or in the time you selected in the Setup mode).

# To Cancel a Test Reminder Alarm:

Press **M** to enter the meter memory. The 14 day average will appear along with the  $\langle \mathbf{O} \rangle$ .

Press **M** again and a box will appear and flash around the

Options

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Using the Markers and Test Reminder Alarm









Using the Markers and Test Reminder Alarm

# Using the Memory:

With the meter off, press the **M** button on the meter to view stored test results.

The **14 day average** will appear on the display with the average for test results taken over the last 14 davs. If you have set an alarm that has not sounded yet, you will also see a 🔞 symbol.

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Number of results: The number of results included in the average is shown at the top of the display. Your control results are not included in this 14 day average.

#### Press $\blacktriangle$ to view the 7 day total.

7 day total: Your meter will display the total number of results taken during the last seven days.



High and low results: At the top of the display you will see the number of high results (above 180 mg/dL) and low results (below 72 mg/dL) during that seven day period.

### Press ▼ to review previous results.

Previous results: Results will be shown starting with the most recent. Each result will show the date and time the test was taken. as well as any symbols you chose to mark the test result.

You can press ▲ or ▼ to scroll forward or backward through the results. You can press and release the button to view stored results one at a time or you can hold it to move through results continuously.

When **End** appears on the display, you have viewed all of the results in the memory.

The meter will hold 480 results in the memory. When the maximum is reached, the oldest test result will be removed as a new test is completed and saved to the memory.

Press **M** to turn the meter off, or it will automatically turn off after three minutes





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**Viewing Stored Results** 

# **Error Codes and Symbols:**

# If you do not resolve the problem, contact Bayer

WHAT YOU SEE	WHAT IT MEANS	WHAT YOU SHOULD DO
+ (will remain on the display)	Low batteries.	Replace the batteries as soon as possible to avoid the risk of a test result not being stored in your meter. Call Bayer Diabetes Care Customer Service at 1-800-348-8100 for free replacement batteries.
(will flash for 10 seconds then the meter will turn off)	Dead batteries.	Replace the batteries immediately to avoid the risk of a test result not being stored in your meter.
, <b>k</b> 1	Temperature out of range.	Move to an area that is within the operating range for the meter (41°F – 113°F). Let the meter adjust to this temperature for twenty minutes before testing.
¥́2 ∃■	The test strip has not filled with enough blood for an accurate test.	Remove the test strip and retest using a new test strip.
¥3	The meter is de- tecting a used test strip or blood was applied before the meter was ready.	Remove the test strip and retest using a new test strip. Wait until you see the flashing blood drop on the display before adding the blood sample.
¥4	Test strip is not inserted correctly.	Remove and reinsert the test strip properly (see page 9).
È5 È9 È6 È12 È8 È13	Potential software or hardware issue.	Remove the test strip and retest using a new test strip. If you continue to have problems, contact Bayer Diabetes Care Customer Service.
	Wrong test strip.	Remove the test strip and retest using a <i>CONTOUR®</i> test strip.

## Diabetes Care Customer Service at 1-800-348-8100

WHAT YOU SEE	WHAT IT MEANS	WHAT YOU SHOULD DO		
<b>美10</b>	Invalid date or time.	See Setup instructions (page 25) to set the date and time on your meter. If you continue to have problems, contact Bayer Diabetes Care Customer Service: 1-800-348-8100.		
<u>)</u> दूँ11	Abnormal result.	Remove the test strip and retest using a new test strip. Carefully follow testing instructions in your User Guide. If you continue to have problems, contact Bayer Diabetes Care Customer Service: 1-800-348-8100.		
<u></u> ≰15 ↑	The meter has detected an error and cannot send the result to your Medtronic device.	Turn the Send option off (see page 24), then retest using a new test strip. (You can then manually enter your result into your Medtronic device.) Then contact Bayer Diabetes Care Customer Service. (You can still use your meter for testing, but results cannot be sent to your Medtronic device.)		
н	Test result is above 600 mg/dL.	<ul> <li>Wash your hands and the test site. Repeat the test using a new test strip.</li> <li>If your result is still "HI," contact your physician or health care professional immediately.</li> </ul>		
WARNING: Glucose levels above 250 mg/dL may indicate a potentially serious medical condition.				
LO	Test result is below 10 mg/dL.	<ul> <li>Repeat the test using a new test strip.</li> <li>If your result is still "LO," contact your physician or health care professional immediately.</li> </ul>		
WARNING: Glucose levels below 50 mg/dL may indicate a potentially serious medical condition.				

Need Help? Bayer Diabetes Care: 1-800-348-8100 (available 24 hours a day, 7 days a week)

**Error Codes and Symbols** 

Help

#### If you do not resolve the problem, contact Bayer Diabetes Care Customer Service at 1-800-348-8100 (available 24 hours a day, 7 days a week)

WHAT YOU SEE	WHAT IT MEANS	WHAT YOU SHOULD DO
Test result con- tinues to flash for 60 seconds, then stops.	The Medtronic device did not acknowledge receipt of the test result within 60 seconds.	<ul> <li>Be sure the Medtronic device is located within 4 feet of the CONTOUR® LINK meter.</li> <li>Check that the Medtronic device is set to accept meter results and the meter ID has been programmed into the device.</li> <li>Check the Medtronic device display to determine if the glucose result has been received by the device. If it has not, you can enter the test result manually.</li> <li>If you continue to have prob- lems, contact Bayer Diabetes Care Customer Service.</li> </ul>
Control test result is out-of- range (too high or too low).	<ul> <li>Test strip or control solution is past the expiration date or is past the discard date.</li> <li>Test strip is deter- iorated due to heat or exposure to moisture.</li> <li>Control solution is not at room temp- erature or may not be mixed well.</li> <li>Incorrect control solution was used.</li> </ul>	<ul> <li>Check all expiration dates and discard dates. Do not use expired testing materials.</li> <li>Make sure you are using <i>CONTOUR®</i> control solution.</li> <li>Gently rock the control bottle to ensure the control solution is mixed well.</li> <li>Run another control test.</li> <li>If result is still out of range, retest with a new test strip and new control solution.</li> <li>If result is still out of range, call Bayer Diabetes Care Customer Service.</li> </ul>
Some display segments do not appear when the meter initially turns on.	Possible meter electronics failure.	Compare meter display with the illustration on page 3. If the display is not correct, contact Bayer Diabetes Care Customer Service.
Results are not displayed in expected units of measure mg/dL.	This may affect the way you see your results.	Contact Bayer Diabetes Care Customer Service.

# Symptoms of High or Low Blood Glucose

You can better understand your test results by being aware of the symptoms of high or low blood glucose; this will also help you decide what to do if your results seem unusual.

High blood glucose

• frequent urination

(Hyperglycemia):

excessive thirst

• increased fatigue

blurred vision

hunger

Some of the most common symptoms are:\*

# Low blood glucose (Hypoglycemia):

- shakiness
- sweating
- fast heartbeat
- blurred vision
- confusion
- passing out
- seizure
- extreme hunger
- irritability
- dizziness

# Ketones (Ketoacidosis):

- shortness of breath
- nausea or vomiting
- very dry mouth
- \*For additional information and a complete list of symptoms, contact your health care professional or refer to the website for the American Diabetes Association: www.diabetes.org

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Error Codes and Symbols

Help

# **Changing the Batteries:**

WARNING: When a low battery warning displays on the meter, replace the battery as soon as possible to avoid a test result not being stored in the meter memory.

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Batteries should be replaced when the meter continually displays or the meter briefly flashes and then turns off (See Error Codes and Symbols, page 36).



Press firmly on the battery cover and slide in the direction of the arrow.

NOTE: If you put the new batteries in the meter within 5 minutes of taking the old ones out, all your settings and results will be saved. If you take more than 5 minutes, you will need to reset the date and time although your other settings and results will be saved.

Remove the old batteries by pressing the top of the battery which will raise the bottom of the battery up.

Place new batteries under the prongs and into the battery compartment with the "+" side up. (Battery part numbers are DL2032 or CR2032.) Slide the battery cover back into place, lining up with the open slots, and close firmly.



WARNING: Keep batteries away from children. Lithium batteries are poisonous. If swallowed, immediately contact your physician or poison control center. Discard batteries according to your local environmental regulations.

Bayer offers the Free Batteries for Life program. When your batteries are low, please call 1-800-348-8100 (available 24 hours a day, 7 days a week) for your free batteries.

## Caring for the System:

- When a low battery warning displays on the meter, replace the battery as soon as possible to avoid a test result not being stored in the meter memory.
- Store the meter in the carrying case provided whenever possible.
- Wash your hands and dry thoroughly before handling to keep the meter and test strips free of oils and other contaminants.
- Handle the meter carefully to avoid damaging the electronics or causing other malfunctions.
- Avoid exposing the meter and test strips to excessive humidity, heat, cold, dust, or dirt.

Please see page 16 for details on cleaning and disinfecting your meter.

**Changing the Batteries** 

Technical Information

For complete instructions on disinfecting and cleaning your meter and lancing device, please see page 16. WARNING: Do not allow solution to run down into the test strip port or around the buttons. Doing so may cause a malfunction.

#### Transferring Results to a Computer:

You can easily transfer test results from the CONTOUR® LINK meter to a computer that includes the Bayer's GLUCOFACTS® DELUXE Diabetes Management



CareLink<sup>®</sup> Therapy Management Software. The results can then be

Software or Medtronic

summarized into easy-to-read reports that you can share with your physician. A Bayer data cable is required to use this feature.

IMPORTANT: The CONTOUR LINK meter has not been tested for use with any diabetes management software other than Bayer's GLUCOFACTS® DELUXE diabetes management software or CareLink® software. Bayer is not responsible for any erroneous results from the use of other software.

For more information, call our Bayer Diabetes Care Customer Service at 1-800-348-8100 (available 24 hours a day, 7 days a week), or visit our website at www.bayerdiabetes.com/us.

For CareLink information, visit www.medtronicdiabetes.com.

**NOTE:** If the cable is connected to the data port (even if the cable is not connected to a PC), results will NOT be sent to the Medtronic device.

# **Technical Information:**

#### Accuracy

Diabetes experts have suggested that glucose meters should agree within 15 mg/dL of a laboratory method when the glucose concentration is lower than 75 mg/dL, and within 20% of a laboratory method when the glucose concentration is 75 mg/dL or higher. The chart below displays how often the *CONTOUR*<sup>®</sup> *LINK* meter achieves this goal. The chart is based on a study done on 100 patients to see how well the *CONTOUR LINK* compared to laboratory results.

For glucose results lower than 75 mg/dL, the percent (and number) of meter results that match the laboratory method within 15 mg/dL :	98.7% (75/76)
For glucose results at 75 mg/dL or higher, the percent (and number) of meter results that match the laboratory method within 20%:	98.5% (319/324)

Note: When meter results are compared to the laboratory results, results below 75 mg/dL are compared in mg/dL.

# Precision

To assess precision under repeatability conditions, venous human blood samples were pooled and adjusted to a hematocrit of 40%. Blood was collected in tubes using sodium heparin as the anticoagulant. The glucose levels of the test solutions were prepared either by allowing samples to age to a final concentration or by using the aqueous 20% glucose solution to adjust the final test concentration. Five glucose levels were evaluated.

For each of 3 lots of sensors, ten *CONTOUR LINK* instruments were tested with ten replicates. In total three hundred replicates were used for each blood glucose level. The mean blood glucose levels, pooled standard deviations and %CVs were calculated and are presented here.

Glucose Level (mg/dL)	45	80	130	194	317
Pooled SD	1.6	2.5	4.0	4.8	8.5
%CV	3.5	3.2	3.1	2.5	2.7

To assess intermediate measurement precision, the performance of ten *CONTOUR® LINK* meters was evaluated with three lots of sensors. The evaluation was performed by three operators who utilized three liquid control glucose levels under normal conditions of use over the course of 10 days. In total, three hundred sensors were used for each glucose level. The Grand Mean, pooled standard deviation and pooled %CV for each glucose level were calculated and are presented here.

Glucose Level (mg/dL)	ucose Level Glucose " Level g/dL) (mg/dL)		Pooled CV (%)
Low (30-50)	39.9	0.8	1.9
Normal (96-144)	123.6	2.1	1.7
High (280-420)	360.7	6.6	1.8

# **Specifications:**

Test Sample: Whole blood

Test Result: Referenced to plasma/serum glucose

Sample Volume: 0.6 µL

Measuring Range: 20- 600 mg/dL

Measuring Time: 5 seconds

Memory Feature: Stores most recent 480 test results

Radio Frequency: 916.5 MHz

Battery Type: Two 3-volt lithium batteries (DL2032 or CR2032)

## **Battery Life:**

Send option off: About 1000 tests (1 yr. average use).

Send option on: About 244 tests (2 months at 4 transmitted results per day).

Meter Life: 5 years

Operating Temperature Range: 41°F–113°F

Humidity: 10-93% RH

Altitude: Up to 11,000 feet does not significantly affect results.

**Dimensions:** 77 mm (H) x 57 mm (W) x 23 mm (T)

Weight: 1.85 ounces

Alarm: "Beeps" whenever a test strip is inserted into or removed from the meter, when the test strip is filled with blood or control solution, and when a test result appears in the display. Two beeps will sound for an error. Twenty beeps will sound when a programmed alarm goes off.

Extras

**Technical Information** 

### Warranty:

**Manufacturer's Warranty:** Bayer HealthCare warrants to the original purchaser that this instrument will be free from defects in materials and workmanship for 5 years from the date of original purchase (except as noted below). During the stated 5-year period, Bayer HealthCare shall, at no charge, replace a unit found to be defective with an equivalent or current version of the owner's model.

**Limitations of Warranty:** This warranty is subject to the following exceptions and limitations:

- **1.** A 90-day warranty only will be extended for consumable parts and/or accessories.
- 2. This warranty is limited to replacement due to defects in parts or workmanship. Bayer HealthCare shall not be required to replace any units which malfunction or are damaged due to abuse, accidents, alteration, misuse, neglect, maintenance by someone other than Bayer HealthCare, or failure to operate the instrument in accordance with instructions. Further, Bayer HealthCare assumes no liability for malfunction or damage to Bayer HealthCare instruments caused by the use of reagents other than reagents (i.e., CONTOUR® test strips) manufactured or recommended by Bayer HealthCare.
- **3.** Bayer HealthCare reserves the right to make changes in design of this instrument without obligation to incorporate such changes into previously manufactured instruments.
- 4. Bayer HealthCare has no knowledge of the performance of the CONTOUR® LINK blood glucose meter when used with any test strips other than CONTOUR test strips, and therefore makes no warranty of the performance of the CONTOUR LINK meter when used with any test strips

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other than *CONTOUR*<sup>®</sup> test strips or when the *CONTOUR* test strip is altered or modified in any manner.

**5.** Bayer HealthCare makes no warranty of the performance of the *CONTOUR*<sup>®</sup> *LINK* meter or test results when used with any control solution other than *CONTOUR* control solution.

BAYER HEALTHCARE MAKES NO OTHER EXPRESS WARRANTY FOR THIS PRODUCT. THE OPTION OF REPLACEMENT, DESCRIBED ABOVE, IS BAYER HEALTHCARE'S ONLY OBLIGATION UNDER THIS WARRANTY. IN NO EVENT SHALL BAYER BE LIABLE FOR INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES, EVEN IF BAYER HEALTHCARE HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you. This warranty gives you specific legal rights and you may also have other rights which vary from state to state.

**For warranty service:** Purchaser must contact the Customer Service Department of Bayer Diabetes Care, by calling toll free 1-800-348-8100 (available 24 hours a day, 7 days a week), for assistance and/or instructions for obtaining service of this instrument.

Warranty

# Service Information:

If you have a problem and none of the problem-solving steps in the User Guide help, call Bayer Diabetes Care Customer Service. We have trained specialists to help you.

#### Important:

- Speak with Bayer Diabetes Care Customer Service before returning your meter for any reason. He/she will give you the information needed to get your problem handled correctly and efficiently.
- Have your CONTOUR® LINK blood glucose meter and CONTOUR® test strips available when you phone. It would also be helpful to have a bottle of CONTOUR control solution nearby.

# Supplies:

When calling or writing for supplies, be sure to include the number with the name of the replacement part or accessory item.

# **Replacement Parts**

#### Part

Number*	Item
40030030	3-volt Lithium Battery (DL2032 or CR2032) — 2 (Free Batteries for Life program. Call 1-800-348-8100 [available 24 hours a day, 7 days a week].)
84378888 40453291	CONTOUR <sup>®</sup> LINK User Guide Bayer's USB Data Cable

\* Part numbers are subject to change without notice

#### REFERENCES

- <sup>1</sup> "FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ ucm224025.htm
- <sup>2</sup> "CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010) http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html
- <sup>3</sup> Longo DL, et al: Harrison's Principles of Internal Medicine, 18th edition. 2011: 3003.

Service and Supplies





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