Warranty information and online meter registration available at www.diabetes.ascensia.com/warranty





or call our Customer Service.



- Limitations Serious Illness: The system should not be used to test critically ill patients and should not be used by persons with reduced peripheral blood flow. Inaccurate results may occur in severely hypotensive individuals, those dehydrated or patients in shock. Inaccurate low results may occur for individuals experiencing a hypoxia state, or a hyperglycemic-
- hyperosmolar state, with or without ketosis.^{3,4} • Meter Operating Temperature Range: 41°F–113°F
- Meter Storage Temperature Range: -4°F–149°F Meter Operating Humidity Range: 10% RH–93% RH
- Control Testing Temperature Range: 59°F–95°F • Test Strip Storage Conditions: 41°F–86°F, 10%–80%
- Relative Humidity (RH) • Second-Chance® sampling conditions: Temperature
- Range 59°F–95°F, Hematocrit 20%–55% • Sample Volume: 0.6 μL
- Measuring Range: 20 mg/dL-600 mg/dL of glucose in blood • Altitude: This system has not been tested at altitudes higher than 20,674 feet (6,301 meters). Hematocrit: Contour Next blood glucose test strip results are
- not significantly affected by hematocrit levels in the range of 20% • **Xylose:** Do not use during or soon after xylose absorption
- testing. Xylose in the blood will cause an interference. Neonatal Use: The CONTOUR NEXT GEN meter is not
- **indicated** for neonatal use.

PRECAUTIONS

TESTING

Read your CONTOUR NEXT GEN user guide, the lancing device package insert, if provided, and all instructional materials provided in your meter kit before

CONTACT INFORMATION

Customer Service is available Monday through Sunday, 8:00 am through 12:00 Midnight, Eastern Time. If this is a medical emergency, please contact your health care professional or dial 911. To leave a message for Customer Service, remain on the line. One of our representatives will return your call as soon as possible.

Distributed by Ascensia Diabetes Care US Inc. 5 Wood Hollow Road Parsippany, NJ 07054 www.diabetes.ascensia.com

Customer Service: 1-800-348-8100 For information on patents and related licenses, see www.patents.ascensia.com

Purchase of this product does not alone confer a license to use under any patents. Such a license only arises, and extends only to, when the CONTOUR NEXT GEN meters and CONTOUR NEXT blood glucose test strips are used together. No test strip supplier other than the supplier of this product is authorized to grant such a license.

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testing. Follow all instructions for use and care exactly

Examine the product for missing, damaged, or broken

parts. If the test strip packaging is open or damaged, do

For replacement parts, contact Customer Service. See

Always keep the CONTOUR NEXT blood glucose test strips

bottle immediately after removing a test strip. The bottle is

designed to keep the test strips dry. Do not place or store

exposing meter and test strips to excessive humidity, heat,

could lead to inaccurate results. Do not use a test strip that

Do not use expired materials. Using expired material can

NOTE: If this is the first time you are opening the control

Do not use control solution that is more than 6 months past

Customer Service. See Contact Information. Do not use the

meter for blood glucose testing until you resolve this issue.

at temperatures between 41°F and 113°F. If the meter or test

• The meter is designed to give accurate blood testing results

If your control solution test result is out of range, contact

cause inaccurate results. Always check the expiration

other items or medications in the test strip bottle. Avoid

cold, dust, or dirt. Exposure to room humidity by leaving

the bottle open or not storing the strips in their original

bottle or foil packet can damage your test strips. This

in their original bottle or foil packet. Tightly close the

as described to help avoid inaccurate results.

Your CONTOUR NEXT GEN meter works ONLY

with CONTOUR NEXT blood glucose test strips and

not use those test strips.

CONTOUR®NEXT control solution.

appears damaged or has been used.

solution, write the date on the bottle

the date you first opened the bottle.

dates on your test materials.

Contact Information

ASCENSIA Diabetes Care

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strip is outside this range, you should not test until the meter and test strip are within this range. Whenever the meter is moved from one location to another, allow approximately 20 minutes for the meter to adjust to the temperature of the

Table of Contents

Your meter display

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3 LOGBOOK

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Order meter kit supplies

Accuracy and Precision Meter specifications

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1 GETTING STARTED

Meter symbols and the Home screen

Symptoms of High / Low blood glucose

The smartLIGHT target range indicator

Add a Meal Marker to a blood glucose result

View test results and blood glucose averages

Turn Off smartLIGHT target range indicator

Download the Contour Diabetes app

- new location before performing a blood glucose test. Do not attempt to perform a blood glucose test when the CONTOUR NEXT GEN meter is connected to a computer. Use only approved equipment (for example, USB cable) CONTOUR NEXT blood glucose test strip from the manufacturer or certified body such as UL, CSA,
- Your CONTOUR NEXT GEN meter has been preset and locked to display results in mg/dL (milligrams of glucose per deciliter of blood).

Results in mg/dL do not have a decimal point. Results in mmol/L have a decimal point. Example:

Check your display screen to be sure the results are shown correctly (mg/dL). If not, contact Customer Service. See Contact Information. The CONTOUR NEXT GEN blood glucose monitoring

Ketones (Ketoacidosis):

contact your health care professional.

shortness of breath

nausea or vomiting

- system has a measuring range of 20 mg/dL to 600 mg/dL. For results under 20 mg/dL or over 600 mg/dL: o If your meter does not display a value and displays the LO screen, contact your health care
- professional immediately. If your meter does not display a value and displays the HI screen, wash your hands or the test site and repeat the test with a new strip. If the meter again displays the HI screen, follow medical advice immediately.

very dry mouth

WARNING

critical level you have established with your health care

If you are experiencing any of these symptoms, test

professional or over the recommended limit, follow

your health care professional's advice immediately.

For additional information and a complete list of symptoms,

3. When the **Meal Marker** you want is blinking, press **OK**.

4. If this is a **Before Meal** reading, you can set a **Reminder** to

If you do not make a **Meal Marker** selection within 3 minutes,

the meter turns off. Your blood glucose reading is stored in the

1. Make sure the **Reminder** (1) feature is On in **Settings**.

2. Mark a blood glucose reading as a **Before Meal** reading, then

button

Reminder is set.

3. To scroll from 2 hours to 0.5 hours

4. To set the **Reminder**, press **OK**.

The screen returns to the **Before**

Meal reading. The meter displays the

Reminder (1) symbol to confirm the

by half-hour intervals, press the ▲ or

See Section 4 Settings: Set Reminder Feature.

Logbook without a Meal Marker.

Set a Test Reminder

10:45RM 4/12

test your blood glucose later. See Section 2 Testing: Set a Test

your blood glucose. If your test result is under the

INTENDED USE

The CONTOUR NEXT GEN blood glucose monitoring system is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood drawn from the fingertips. The CONTOUR NEXT GEN blood glucose monitoring system is intended to be used by a single person and should not be shared. The CONTOUR NEXT GEN blood glucose monitoring system is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid in monitoring the effectiveness of a diabetes control program. The CONTOUR NEXT GEN blood glucose monitoring system should not be used for the diagnosis of or screening for diabetes or for neonatal use. The CONTOUR NEXT blood glucose test strips are for use with the CONTOUR®NEXT GEN blood glucose meter to quantitatively measure glucose in fresh

The CONTOUR NEXT GEN blood glucose meter is not intended for use with Alternative Site Testing (AST).

The system is intended for in vitro diagnostic use only.

capillary whole blood drawn from the fingertips.

NOTE: This document uses the term 'blood glucose' to mean

IMPORTANT SAFETY INFORMATION

If your blood glucose reading is under the critical level you have established with your health care professional, follow their advice immediately.

device should be disinfected prior to use by the second If your blood glucose reading is over the recommended limit set by your health care professional: 1. Wash and dry your hands well.

2. Retest with a new strip. If you get a similar result, follow your health care professional's advice immediately.

- Talk to Your Health Care Professional: Before setting any **Target Ranges** in your meter or in compatible Ascensia Diabetes Care software.
- Before changing your treatment or medication based on
- If you obtain test results that are not consistent with the way you feel.
- Before making any other decision of medical relevance.

Potential Biohazard

ucm224025.htm

monitoring.html

Your **Logbook**.

Meter Settings

Services; update June 8, 2017."

Symbol | What the Symbol Means

After Meal marker.

Meter is ready to test.

Control solution test result.

A **Target Range** or **Target Range** setting.

Add more blood to **same** test strip.

smartLIGHT[™] target range indicator setting.

Bluetooth® symbol: means the **Bluetooth** wireless

setting is On; the meter can communicate with a

Total number of blood glucose readings used to

No marker selected.

mobile device

Low batteries.

Meter error.

Dead batteries.

Reminder feature.

Sound feature.

ៅ ពីvg | 7-, 14-, 30-, and 90-day averages.

calculate averages.

a ----

 \Box

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

For more information about cleaning and disinfecting

your meter or lancing device see: "US Food and Drug

than one person poses risk for transmitting bloodborne

http://wayback.archive-it.org/7993/20170111013014/http://

www.fda.gov/MedicalDevices/Safety/AlertsandNotices/

"Centers for Disease Control and Prevention. Infection

Prevention during Blood Glucose Monitoring and Insulin

Administration. US Department of Health and Human

http://www.cdc.gov/injectionsafety/blood-glucose-

pathogens: initial communication. US Department of

Health and Human Services; update 11/29/2010."

Administration. Use of fingerstick devices on more

- The lancing device usually provided with your kit should not be used for assisted blood draws by health care If your meter is being operated by a second person who is professionals or at health care provision sites. providing testing assistance to you, the meter and lancing Always dispose of used test strips and lancets as medical
- All parts of the kit are considered biohazardous and can All products that come in contact with human blood potentially transmit infectious diseases, even after you should be handled as if capable of transmitting infectious have performed cleaning and disinfection. For complete instructions on cleaning and disinfecting Keep out of reach of children. This kit contains small parts your meter, see Section 5 Help: Cleaning and Disinfection.
 - that could cause suffocation if accidentally swallowed. Keep batteries away from children. Many types of batteries are poisonous. If swallowed, immediately contact your poison control center.

• The meter and lancing device are for single-patient use.

Do not share them with anyone including other family

waste or as advised by your health care professional.

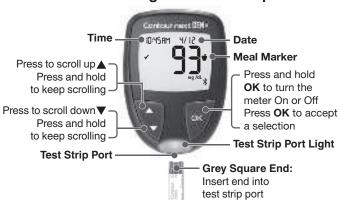
members! Do not use on multiple patients.^{1,2}

- This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not
- been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures.
- Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus

(HBV), or other bloodborne pathogens.

The CONTOUR NEXT GEN blood glucose monitoring system consists of the Contour Next GEN meter, Contour Next blood glucose test strips and the CONTOUR DIABETES app. Your CONTOUR NEXT GEN meter and

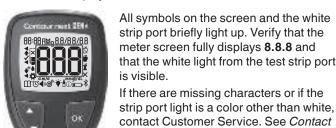
GETTING STARTED



- Sample Tip: Blood sample pulled in here • To exit from the Logbook or Averages and return to the

Check the Meter Display

Press and hold **OK** until the meter turns on, about 3 seconds. The screen displays the **Power On Self Test**.



strip port briefly light up. Verify that the meter screen fully displays 8.8.8 and that the white light from the test strip port If there are missing characters or if the strip port light is a color other than white, contact Customer Service. See Contact Information. This may affect the way you

NOTE: Your meter comes with a pre-set time, date, and target range. You can change these features in Settings. See Section 4 Settings.

see your results.

Your Me	our Meter Symbols		
Symbol	What the Symbol Means		
	Yellow Light: test result is above Target Range.		
	Green Light: test result is in Target Range.		
	Red Light: test result is below Target Range.		
A	To at we wilt in a bassa Toward Dawns		

- Test result is **above** Target Range. Test result is **in** Target Range.
- Test result is **below** Target Range. Test result is above 600 mg/dL.

Test result is below 20 mg/dL

lid immediately after removing a test strip.

Fasting marker. Before Meal marker.

The Home screen has 2 options: Logbook III and Settings ... To highlight the Logbook
 ☐ or **Settings** ♠, press the ▼ button. • To enter the **Logbook**, press **OK** while

The Home Screen

the **Logbook** symbol is blinking. To enter Settings, press OK while the **Settings** symbol is blinking.



test strip.



Second-Chance sampling allows you to apply more blood to the same test strip if the first blood sample is not enough. Your test strip is designed to easily 'sip' the blood into the sample tip. Do not drop blood directly on the flat surface of the

Get Ready to Test

Read your CONTOUR NEXT GEN user guide, the lancing device package insert, if provided, and all instructional materials provided in your meter kit before testing. Examine the product for missing, damaged, or broken parts. If the test strip packaging is open or damaged, do not use those

test strips. For replacement parts, contact Customer Service. See Contact Information. CAUTION: Your CONTOUR NEXT GEN meter works only with

CONTOUR NEXT blood glucose test strips and CONTOUR NEXT

Fingertip Testing

control solution.

Ensure that you have the materials you need before you begin testing:

 CONTOUR NEXT blood glucose test strips. Lancing device and lancets from your kit, if provided.

Some supplies are sold separately. See Section 6 Technical

You can attach a **Meal Marker** to your blood glucose result

Your CONTOUR NEXT GEN meter comes with Meal Markers

Symbol What It Means Target Range

turned Off. You can turn Meal Markers On and change Target

after fasting (no food result against the **Before**

within 1 hour before result against the **Before**

except water or non- (Pre-set to 70 mg/dL-

the first bite of a meal. | Meal Target Range.

Use when testing at The meter compares your

times other than after | result against the **Overall**

fasting or before or **Target Range**.

The meter compares your

The meter compares your

Meal Target Range.

(Pre-set to 70 mg/dL-

The meter compares your

result against the **After**

(Pre-set to 70 mg/dL-

(Pre-set to 70 mg/dL-

Meal Target Range.

130 mg/dL)

130 mg/dL)

180 mg/dL)

180 mg/dL)

- CONTOUR NEXT GEN meter.
- To perform a quality control check, see Section 5 Help: Control Solution Testing.

Information: Customer Service Checklist.

About Meal Markers

when the Meal Marker feature is turned On.

Use when testing

or drink for 8 hours,

caloric beverages).

Use when testing

Use when testing

within 2 hours after

a meal

Ranges in Settings . See Section 4 Settings.

WARNING: Potential Biohazard All parts of the kit are considered biohazardous and can

- potentially transmit infectious diseases, even after you have performed cleaning and disinfection. See Section 5
- meter, lancing device, or test strips.
- meter, see Section 5 Help: Cleaning and Disinfection.

the symptoms of high or low blood glucose. According to the most common symptoms are:

Low blood glucose (Hypoglycemia): shakiness

 sweating · fast heartbeat blurred vision

About Meal Markers.

Example:

Marker Feature

confusion

 irritability extreme hunger dizziness

- Help: Cleaning and Disinfection.
- Always wash your hands with antibacterial soap and water and dry them well before and after testing or handling the
- For complete instructions on cleaning and disinfecting your

High / Low Blood Glucose

Symptoms of High or Low Blood Glucose

You can better understand your test results by being aware of American Diabetes Association (www.diabetes.org), some of the

- 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

Add a Meal Marker to a Reading

For more information, see Section 2 Testing:

During a blood glucose test, if **Meal Markers** are On, you can

You cannot select a Meal Marker in the Settings screen.

select a **Meal Marker** when the meter displays your result.

- seizure
- passing out

Do not press OK or remove

You can select the blinking

marker or choose a different

the test strip yet.

Meal Marker.

High blood glucose (Hyperglycemia): **Prepare the Lancing Device** frequent urination increased fatigue

excessive thirst hunger blurred vision

- The lancing device usually provided with your kit is intended blood draws by health care providers or at health care
- else, even a family member, due to risk of infection. Do not reuse lancets. Used lancets are not sterile. Use a new lancet each time you test. If your meter is being operated by a second person who

Home screen, press **OK**.

• When a symbol is blinking, you can select it.

CAUTION: Do not use expired materials. Using expired material can cause inaccurate results. Always check the

Refer to your lancing device insert for detailed instructions on preparing the lancing device and fingertip testing.

WARNING: Potential Biohazard

- for single-patient use only. It should not be used for assisted provision sites, and should never be shared with anyone
- is providing testing assistance to you, the meter and lancing device should be disinfected prior to use by the second person. Always dispose of used test strips and lancets as medical

Insert the Test Strip

Below Target **▼**.

the CONTOUR DIABETES app.

red and the meter beeps twice.

Reminder set:

expiration dates on your test materials.

smartLIGHT target range indicator

When your blood glucose test is complete, the meter displays

your result with the units, time, date, meal marker (if selected),

Example: Blood test result with **Meal Marker** selected and a

NOTE: To change a Meal Marker you selected, you must use

If the **smartLIGHT** setting is On, the test strip port displays a

color representing your result value compared to your **Before**

If your blood glucose result is below target, the **smartLIGHT** is

If you do not select a **Meal Marker**, your blood glucose test

result is compared to an Overall Target Range.

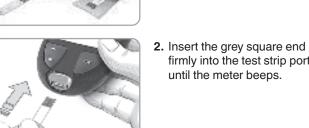
Meal, After Meal, or Overall Target Range.

and target range symbol: Above Target ♠, In Target ✔, or

waste or as advised by your health care professional.



NOTE: If test strips are stored in a bottle, tightly close the bottle



To move to the **Home**

screen, press OK.

Blood glucose test is complete.

Test Results

professional:

10:45RM 4/12

The screen displays the blinking blood

drop indicating it is ready to test a blood

firmly into the test strip port

NOTE: After you insert the test strip, apply blood to the test strip within 3 minutes or the meter turns off. Remove the test strip and reinsert it to begin a test.

drop.

Get the Blood Drop: Fingertip Testing

WARNING: Potential Biohazard Always wash your hands with antibacterial soap and water and dry them well before and after testing or handling the

meter, lancing device, or test strips. 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.

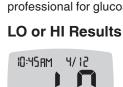


The blood is drawn into the test strip through the tip. 3. Hold the tip of the test strip in the blood drop until the meter

00:60

strip until you select a Meal Marker.

Blood glucose values will vary depending on food intake,



in the fasting state and less than 140 mg/dL in the postprandial state (after a meal).⁵ You should consult with your health care professional for glucose values specific to your needs.



your blood glucose reading is under 20 mg/dL. Contact your health care professional immediately. If your meter does not display a value

value and displays the LO screen,

If your meter does not display a

Eject and Dispose of the Used Lancet



2. Refer to the separate lancing device insert, if provided with your kit, for instructions on automatic ejection of the lancet.

CAUTION: Do not press the

tip of the test strip against the

skin or place the blood on top

of the test strip. This could

lead to inaccurate results or

errors.

1. If the meter beeps twice and the screen

2. Apply more blood to the same test strip

NOTE: If the screen displays an E 1 error

message, remove the strip and start with a

displays a blinking blood drop with a plus

sign, the test strip does not have enough

Second-Chance sampling—Apply More Blood

within 60 seconds.

new strip.

single-patient use. Do not share them with anyone including other family members. Do not use on multiple patients. 1,2

WARNING: Potential Biohazard

should be handled as if capable of transmitting infectious diseases. Always dispose of used test strips and lancets as medical waste or as advised by your health care

Do not reuse lancets. Used lancets are not sterile.

Always wash your hands with antibacterial soap and

water and dry them well before and after testing or

Use a new lancet each time you test.

Fasting

Before

Meal

After

Meal

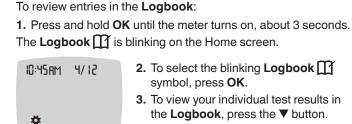
LOGBOOK

Review the Logbook

No Mark | after a meal.

The **Logbook** contains blood glucose test results and their Meal Markers. When the **Logbook** reaches the maximum 800 results, the oldest test result is removed as a new test is completed and saved to the Logbook.

NOTE: To return to the Home screen while viewing the Logbook,



press **OK**.

symbol, press OK. 3. To view your individual test results in the **Logbook**, press the ▼ button.

4. To scroll through your test results,

To scroll faster, press and hold the

press the ▲ or ▼ button.

or ▼ button.



To turn **Meal Markers** On, see Section 4 Settings: Set Meal

1. If the blinking **Meal Marker** is the one you want, press **OK**

2. To select a different **Meal Marker**, press the ▲ or ▼ button

Before Meal

No Mark

ॉ — After Meal

on the meter to scroll between markers.

If you see a LO or HI test result, go to Section 2 Testing: LO or HI Results for more information. 5. To go back to the beginning to review entries, press **OK** to go to the **Home** screen, then select the **Logbook M** symbol.

View Averages

7-day Number

press OK.

1. To enter the **Logbook** from the Home screen, press **OK** while the **Logbook M** is blinking. 2. To view your Averages, press the ▲ button from the *first* Logbook screen.

Average of tests 3. To scroll through your 7-, 14-, 30-, and 90-day Averages, press the ▲ button. 4. To return to your Logbook readings, press the ▼ button on the 7 d Avg (7-day Average).

5. To exit Averages and return to the **Home** screen at any time,

SETTINGS

In **Settings** you can personalize:

 Time format and time. • Date format and date. Sound · Meal Markers.

moving to the next setting.

Access Settings

• smartLIGHT feature.

10:45 PM 4/12 2. To highlight the **Settings** symbol **☼**, press the ▼ button. 3. When the Settings symbol is blinking,

press **OK** to enter **Settings**.

 Reminder feature. Target Ranges.



meter turns on.

Bluetooth wireless functionality. *****O**◆**)**ø*** **♦ NOTE:** Press **OK** to accept the current or changed setting before



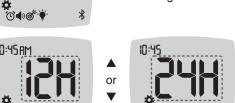
4. To scroll through **Settings** options as shown in the image, press the ▲ or ▼ button until the symbol you want is blinkina.

symbol is blinking. 7. Press OK.

Change the Time

NOTE: If you are in a setting such as Date and you need to exit,

press **OK** repeatedly until you get back to the **Home** screen.



Time Format

3. To change the time format, if needed, press the ▲ or ▼ button, 3. To select Month/Day/Year (m/d) or Day.Month.Year (d.m), then press **OK**.



6. For a 12-hour time format, select AM or PM, as needed, then press OK.

Change the Date

press OK to enter Settings 2. When you are on the **Settings** screen, press the **▼** button

until the current date is blinking, then press **OK**. 12. 4.00 d.m

The date format (m/d or d.m) is blinking.

NOTE: If the **Meal Marker** feature is On, do not remove the test

medication dosages, health, stress, or activity. Nondiabetic plasma glucose concentrations should be less than 100 mg/dL

Expected Test Result Values



and displays the **HI** screen, your blood

glucose reading is over 600 mg/dL.

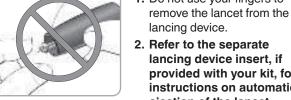
Wash your hands or the test site and

repeat the test with a new strip. If the

meter again displays the **HI** screen,

follow medical advice immediately.

1. Do not use your fingers to



• The lancing device, lancets, and test strips are for

All products that come in contact with human blood

handling the meter, lancing device, or test strips.





1. From the **Home** screen, select the **Settings** is symbol and

messages override any Sound setting. When **Sound** is On:

Your meter comes with the **Sound** turned On. Certain error

NOTE: Some sounds remain On even when you turn the Sound feature Off. To turn sounds Off for a below-target blood glucose reading, turn the **smartLIGHT** feature to Off.

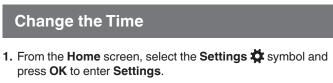
TURN OVER TO SEE BACK

November 28, 2024 4:47 PM

Redmond, WA 98052 T: 425-881-5454 **Production** NEW BAN#: 90013664 Rev. 11/24 CLIENT: Ascensia Diabetes Care PREVIOUS BAN#: 90010655 DESCRIPTION: Contour Next GEN Meter BW UG Pamphlet Alt#1 - 11/28/24 Unmasking & Copy Changes MARKET(S): United States SGK JOB#: 403929668 SKU# / P. BAN#: MULTI / MULTI **DIMENSIONS:** 673 mm (W) x 764 mm (H) PRINTER SPEC: 101005614 REV D BARCODE: 90013664 (2D Matri COLORS: Black

Settings: Change Before/After Meal Target Ranges. To change the Overall Target Range, see Section 4 Settings: Change Overall Target Range. 10:45AM 4/12







ARTWORK ROUTING FOR APPROVAL

if your test results are not consistent with the way If your blood glucose reading is under the critical level you have established with your health care professional, follow their advice immediately.

WARNING

Always consult your health care professional before

changing your medication based on test results or

If your blood glucose reading is over the

If you get a similar result, follow your health care

1. Wash and dry your hands well.

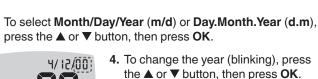
2. Retest with a new strip.

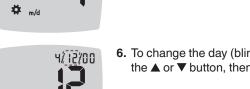
professional's advice immediately.

recommended limit set by your health care

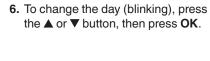
To turn the meter off,

remove the test strip.





(4)/ 12/00



5. To change the month (blinking), press

the ▲ or ▼ button, then press **OK**.



4. Press OK.



Set the Sound

 One long beep indicates a confirmation. Two beeps indicate an error or something that needs your

Master Template No: CTS-176_Rev02 NOTE: THIS COLOR PROOF INDICATES COLOR BREAK ONLY AND MAY NOT ACCURATELY REFLECT ACTUAL PRODUCTION COLOR. V-1 LANGUAGE(S): ENGLISH

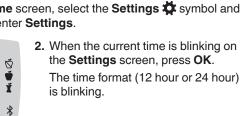
NOTE: To change an individual target range, see Section 4

Yellow means Above Target •

Red means Below Target -

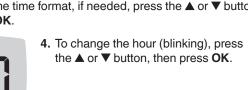
Green means In Target

◆)@*** **6.** To exit from the **Settings** menu and return to the **Home** screen, press the ▲ or ▼ button until the **Settings**



24 Hour

(10)45RM



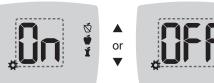


1. From the **Home** screen, select the **Settings** 🕸 symbol and

Date Format

∯ m/d

90013664_CntrNxtGEN_BW_UG_EN_F1B1_v1.indd



Meal Marker Symbols: 🚫 👚 🖠

Your meter comes with the Meal Marker feature turned Off. 3. To turn Meal Markers On or Off, press the ▲ or ▼ button. 4. Press OK.

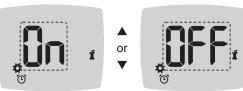
NOTE: When the Meal Marker feature is On, you can select a Meal Marker during a blood glucose test.

When **Meal Markers** are On, you can set a **Reminder** to test your blood glucose after you mark a reading as Before Meal. If **Meal Markers** are Off, see Section 4 Settings: Set Meal Marker

Set Reminder Feature

1. From the **Home** screen, select the **Settings** symbol and press OK to enter Settings. **2.** When you are on the **Settings** screen, press the \blacktriangledown button

repeatedly until the **Reminder** (1) symbol is blinking, then press **OK**. Your meter comes with the **Reminder** feature turned Off. 3. To turn the **Reminder** feature On or Off, press the ▲ or ▼



Reminder Symbol: (5) 4. Press OK

Discuss your Target Range settings with your health

Change Overall Target Range

Your meter provides a pre-set **Overall Target Range**. You can change the Overall Target Range in Settings. 1. From the **Home** screen, select the **Settings** symbol and

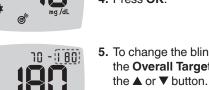
press **OK** to enter **Settings**. 2. When you are on the **Settings** screen, press the **▼** button repeatedly until the **Target** of symbol is blinking, then press OK.

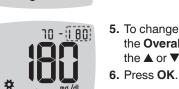


3. To change the blinking Low end of the **Overall Target Range**, press the \triangle or ∇ button.



4. Press OK.





5. To change the blinking **High** end of the Overall Target Range, press

the CONTOUR DIABETES app.

press **OK** to enter **Settings**.

Before Meal/After Meal Low Target

The **Before Meal** 🍎 / **After Meal** 🎽 **Low** Target number is blinking. NOTE: There is only 1 Low number for both the **Before Meal** * and After Meal Target Ranges.

3. To change the blinking Low for both Target Ranges, press the ▲ or ▼ button. 4. Press OK.

Change Before/After Meal

When the **Meal Marker** feature is On, you have 2 Target

same as Fasting) and an After Meal Target Range.

Ranges on your meter: a Before Meal Target Range (the

You can change these ranges in **Settings** in your meter and in

1. From the **Home** screen, select the **Settings** 🌣 symbol and

2. When you are on the **Settings** screen, press the ▼ button

repeatedly until the **Target** of symbol is blinking, then

arget Ranges

Before Meal High Target



5. To change the blinking **High** end of the **Before Meal Target Range**, press the \blacktriangle or \blacktriangledown button.

Set smartLIGHT target range

7. To change the blinking High end

press the ▲ or ▼ button.

of the After Meal Target Range,

Your meter comes with the **smartLIGHT** target range indicator turned On. When this feature is On, the test strip port light displays a color that corresponds to your test result.

8. Press OK.

for a blood glucose reading marked as **Fasting**.



After Meal High Target

Red means Below Target **T** 1. From the **Home** screen, select the **Settings** symbol and

press **OK** to enter **Settings** 2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **smartLIGHT** * symbol is blinking, then press OK.



smartLIGHT Symbol: -

NOTE: The Before Meal Target Range is also the Target Range 3. To turn the smartLIGHT feature On or Off, press the ▲ or ▼ button to display the option you want. 4. Press OK.

Set Bluetooth Wireless Functionality

After pairing your meter with a mobile device, you can turn the **Bluetooth** setting On or Off. For pairing instructions, see Section 4 Settings: Pairing Mode

1. From the **Home** screen, select the **Settings** symbol and

press OK to enter Settings

2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Bluetooth** \$\\$\ symbol is blinking, then press **OK**.

3. To turn **Bluetooth** wireless functionality On or Off, press the ▲ or ▼ button. 4. Press OK.

Clean and disinfect your meter once a week.

• Clorox Healthcare Bleach Germicidal Wipes containing 0.55%

CAUTION: Do not allow cleaning solution to run into the

meter through open areas, such as around the buttons or the

1. Before disinfecting, clean the meter as described in *Cleaning*

2. Using a new germicidal wipe, carefully wipe all outer surfaces

NOTE: For proper disinfection, you must keep all meter surfaces

Disinfecting Your Meter

Supplies needed for disinfecting:

sodium hypochlorite (bleach).

meter's test strip or USB port.

of your meter until wet.

wet for 60 seconds

Paper towels.

Timing device.

The CONTOUR DIABETES app for Your

CONTOUR DIABETES app

CONTOUR NEXT GEN meter Your CONTOUR NEXT GEN meter is designed to work with the CONTOUR DIABETES app and your compatible smartphone or tablet. Visit **compatibility.contourone.com** for a list of compatible operating systems that work with the

CONTOUR DIABETES app. Check this list before upgrading your operating system.

You can do the following with your CONTOUR DIABETES app: Add Notes after testing that help to explain your results.

Set testing reminders.

· Access easy-to-read graphs of test results over a day or over a

period of time.

Share reports.

Change meter settings, as necessary.

The CONTOUR DIABETES app: Automatically stores your results.

 Saves your Notes in My Readings. Displays your trends and test results as they compare with your targets.

• Syncs your most recent Target Range from the app or meter, across the system.

Syncs the app date and time to your meter.

Download the Contour Diabetes app

3. Install the Contour Diabetes app.

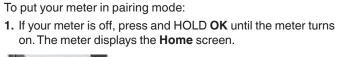
1. On your compatible smartphone or tablet, go to the App Store[®] or the Google PlayTM store. 2. Search for the CONTOUR DIABETES app.

CAUTION: The CONTOUR NEXT GEN meter has not been tested for use with any software other than compatible Ascensia Diabetes Care software. The manufacturer is not responsible for any erroneous results from the use of other software.

Pairing Mode

CAUTION: There is a remote possibility that a computer specialist could listen in on your wireless communications when you pair the blood glucose meter and would then be able to read your blood glucose readings from your meter. If you believe this is a risk, pair your blood glucose meter far away from other people. After you pair your device, you do not need to take this precaution.

To pair your meter with the CONTOUR DIABETES app, download the app and follow the instructions to *Pair a Meter*.





2. Press and HOLD the ▲ button for about 3 seconds, until you see the blinking **Bluetooth** symbol (as shown in the next step). A blue light blinks when you are in pairing mode.

3. When the meter displays the serial number, follow the instructions on the app to match the meter serial number. Meter serial number

Example: Your meter in pairing mode.

Pass code CO dE | 89 12 34

When a connection is made, the meter displays the 6-digit pass code. 4. Enter the pass code on the smart device.



NOTE: You can update your Target Ranges from the meter or

from the app. The most recently changed Target Ranges will

Bluetooth

update in the meter and the app when they are synced.

HELP

Meter Care Caring for your meter:

or causing other malfunctions.

• Store the meter in the carrying case provided, whenever

• Wash and dry hands well before handling to keep the meter and test strips free of water, oils, and other contaminants.

Handle the meter carefully to avoid damaging the electronics

• Avoid exposing your meter and test strips to excessive humidity, heat, cold, dust, or dirt. • Clean and disinfect your meter as recommended in the next

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

or display. Your CONTOUR NEXT GEN meter has been tested for 260 cycles of cleaning and disinfection (equivalent to one cycle per week for 5 years). This device has been demonstrated to withstand 5 years of cleaning and disinfection without damage, by a disinfectant that is effective against common microbial and viral pathogens. You should call Customer Service for assistance if your device malfunctions for any reason or if you notice any changes in the external meter case or display. See Contact Information.

Cleaning and Disinfection

single-patient use only.

 Always wash your hands with antibacterial soap and water and dry them well before and after testing or handling the meter, lancing device, or test strips. If your meter is being operated by a second person who is providing testing assistance to you, the meter and lancing

WARNING: Potential Biohazard All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have

device should be disinfected prior to use by the second

person. The meter and lancing device are intended for

performed cleaning and disinfection. Clean and disinfect your CONTOUR NEXT GEN meter once a week. Use only Clorox Healthcare Bleach Germicidal Wipes (EPA #67619-12) containing 0.55% sodium hypochlorite

(bleach). The wipes are proven safe to use with the CONTOUR NEXT GEN meter. Clorox Healthcare Bleach Germicidal Wipes (EPA #67619-12) are available for purchase online at http://www.officedepot.com or http://www.amazon.com. For technical assistance or questions on cleaning and disinfection, call Customer Service: 1-800-348-8100.

 Cleaning involves the removal of visible dirt and debris, but does not reduce the risk for transmission of infectious diseases. • **Disinfecting** (if performed properly) reduces the risk of

Evaluate your device after performing cleaning and disinfection to ensure that the procedure does not cloud the face/display of the meter and does not corrode or erode the plastic housing or buttons. For more information

on more than one person poses risk for transmitting bloodborne pathogens: initial communication. US Department of Health and Human Services; update 11/29/2010. http://wayback.archive-it. org/7993/20170111013014/http://www.fda.gov/MedicalDevices/ Safety/AlertsandNotices/ucm224025.htm Centers for Disease Control and Prevention. Infection Prevention

during Blood Glucose Monitoring and Insulin Administration.

2017. http://www.cdc.gov/injectionsafety/blood-glucose-

US Department of Health and Human Services; update June 8,

US Food and Drug Administration. Use of fingerstick devices

monitoring.html **Cleaning Your Meter**

meter's test strip or USB port.

Clean and disinfect your meter once a week. Supplies needed for cleaning: • Clorox Healthcare Bleach Germicidal Wipes containing 0.55%

sodium hypochlorite (bleach). Paper towels. **CAUTION:** Do not allow cleaning solution to run into the

1. Carefully clean the meter with germicidal wipes until all soil

meter through open areas, such as around the buttons or the

is removed. 2. Dry as necessary with a clean paper towel.

3. After keeping the meter wet for 60 seconds, use a clean paper

towel to dry the meter surfaces and the test strip port.

Cleaning and Disinfecting Your Lancing Device

for detailed instructions for cleaning and disinfecting

Refer to the lancing device insert provided with your kit

Transfer Results to a Personal Computer

CAUTION: Do not attempt to perform a blood glucose test when the CONTOUR NEXT GEN meter is connected to a

computer. You can transfer test results from the CONTOUR NEXT GEN meter to a computer where they can be summarized in a report with graphs and tables. To make use of this feature, you need

diabetes management software and a 1-meter (or 3-foot) long

USB-A to Micro USB-B cable. This type of cable is available in

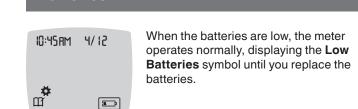


Ensure your meter's USB port door is completely closed when not in use.

USB Port

CSA, TUV, or CE.

CAUTION: Use only approved equipment (for example, USB cable) from the manufacturer or certified body such as UL,



When you are no longer able to perform a test, the meter displays the **Dead** Batteries screen. Replace the batteries immediately.

Replace the Batteries



Testing Errors

System Errors

See Contact Information.

Testing Error

Meter software

1. Turn off your meter. 2. Turn the meter over and slide the battery cover in the direction of the arrow.

3. Remove both of the old batteries and replace them with two 3-volt CR2032 or DL2032 coin cell batteries.



4. Make sure the '+' sign is facing up on the new batteries. 5. Press each battery into a compartment.

6. Slide the battery cover back into place. 7. Discard old batteries according to your local environmental regulations.

WARNING Keep batteries away from children. Many types of batteries are poisonous. If swallowed, immediately

contact your poison control center.

NOTE: Always check the date and time after you replace

Control Solution



CAUTION: Use only CONTOUR NEXT control solution (Level 1 and Level 2) with your CONTOUR NEXT GEN blood glucose monitoring system. Using anything other than CONTOUR NEXT control solution can

cause inaccurate results.

 You think your test strip may be damaged. • You think your meter may not be working properly. You have repeated, unexpected blood glucose results.

WARNING

Do not calibrate your continuous glucose monitoring

Do not calculate an insulin dose based on a control

You should perform a control test when:

device from the control result

WARNING

transmitting infectious diseases.

CAUTION: Do not use expired materials. Using expired material can cause inaccurate results. Always check the expiration dates on your test materials.

Refer to your control solution insert. Level 1 and Level 2 control solutions are available and sold separately. You should test your CONTOUR NEXT GEN meter with control solution only when the temperature is 59°F-95°F. Store control solutions between 48°F and 86°F. Contact Customer Service for more information on how to purchase control solution. See Contact Information.

Control Solution Testing NOTE: Tightly close the bottle lid immediately after you remove

the test strip. 1. Remove a CONTOUR NEXT blood glucose test strip from the bottle or foil packet.

2. Insert the grey square end of the test strip into the test strip port until the meter beeps.

The meter turns on, displaying a test strip with a

CAUTION: Do not use control solution that is more than

NOTE: If this is the first time you are opening the control solution, write the date on the bottle.

6 months past the date you first opened the bottle.

flashing blood drop.



3. Shake the control solution bottle well, about 15 times before every use. Unmixed control solution may cause inaccurate results.

4. Remove the bottle cap and use a tissue to wipe away any solution around the bottle tip before dispensing a drop. 5. Squeeze a small drop of solution onto a clean, nonabsorbent

CAUTION: Do not apply control solution to your fingertip or to the test strip directly from the bottle.

6. Immediately touch the tip of the test strip to the drop of control solution. 7. Hold the tip in the drop until the meter beeps.

The meter counts down for 5 seconds before the meter displays the control test result. The meter automatically marks the result as a control test. Control test results are not included in your meter **Logbook**, in blood glucose averages, or in targets in the CONTOUR DIABETES app.

9. Remove the test strip and dispose as medical waste or as advised by your health care professional. If your control test result is out of range, do not use your CONTOUR NEXT GEN meter for blood glucose testing until you resolve the issue. Contact Customer Service. See *Contact*

8. Compare your control test result with the range printed on the

test strip bottle, foil packet, or bottom of the test strip box.

TECHNICAL INFORMATION

Error Detection Displays

The meter screen displays error codes (**E** plus a number) for test result errors, strip errors, or system errors. When an error occurs, the meter beeps 2 times and displays an error code. Press **OK** to turn off the meter.

If you experience continued errors, contact Customer Service. See Contact Information.

Error Code	What It Means	What to Do				
Strip Errors						
E 1	Too Little Blood	Remove the strip. Repeat the test with a new strip.				
E2	Used Test Strip	Remove the strip. Repeat the test with a new strip.				
E 3	Strip Upside Down	Remove the strip and insert it correctly.				
E 4	Wrong Strip Inserted	Remove the strip. Repeat the test with a CONTOUR NEXT blood glucose test strip.				
E 6	Moisture Damaged Strip	Remove the strip. Repeat the test with a new strip.				
E8	Strip or Test Errors	Repeat the test with a new strip. If the error persists,				

Customer Service Checklist

Repeat the test with a new

Turn the meter off. Turn the

meter back on. If the error

strip. If the error persists,

contact Customer Service. Move the meter, strip, and Too Cold to Test control solution to a warmer Control Solution area. Test in 20 minutes. Move the meter, strip, and Too Hot to Test E25 control solution to a cooler Control Solution area. Test in 20 minutes. Move the meter and strip E27 Too Cold to Test to a warmer area. Test in 20 minutes Move the meter and strip Too Hot to Test to a cooler area. Test in

E30-E99 or hardware persists, contact Customer malfunctioned Service. Speak to a Customer Service representative before returning your meter for any reason. Contact Customer Service.

20 minutes

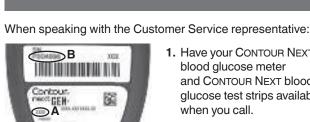


back of the meter. 4. Check the battery status.

the meter (see above). To order parts required for use but not included in your kit.

Sunday, 8:00 am through 12:00 Midnight, Eastern Time.

The following table lists all parts included in this meter kit.



3. Locate the test strips' expiration date on the bottle or foil packet **Meter Kit Contents**

and serial number (B) on the

Required parts that may not be included in your kit are indicated by an asterisk (*). Locate the model number (A) on the back of contact Customer Service at 1-800-348-8100, Monday through

9732 | 7922 | 7383 CONTOUR NEXT GEN blood glucose meter (with two 3-volt CR2032 or DL2032 coin cell batteries) . Have your CONTOUR NEXT GEN CONTOUR NEXT GEN user guide blood glucose meter and Contour Next blood CONTOUR NEXT GEN quick reference guide • glucose test strips available CONTOUR NEXT blood glucose test strips* • when you call. CONTOUR NEXT control solution* 2. Locate the model number (A) MICROLET®NEXT lancing device

MICROLET® lancets

Carrying case

Technical Information: User Accuracy

• | • | •

The CONTOUR NEXT GEN meter results may vary slightly from your actual blood glucose value due to slight differences in testing technique and the natural variation in test technology. The table below shows the results where typical users enrolled in a clinical study used the CONTOUR NEXT GEN meter to measure their blood glucose levels. For example, in this study, the CONTOUR NEXT GEN meter displayed results within 15% of their actual blood glucose level in 366 out of 371 measurements as compared to an approved lab instrument.

Table 1: System accuracy results for glucose concentrations

ss the entire tested range						
fference range ween the actual lood glucose evel and the utour Next GEN meter result	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%		
Percent						

A measurement repeatability study was conducted with the CONTOUR NEXT GEN blood glucose monitoring system using 5 venous whole blood specimens with glucose levels from

Technical Information: Precision

The following precision results were obtained. Table 1: System repeatability results for CONTOUR NEXT GEN meter using CONTOUR NEXT blood glucose test strips 95% CI of 40.1 1.1 1.04-1.23 2.8

(and number) of 64.96% 93.53% 98.65% 99.19% samples within (241/371) (347/371) (366/371) (368/371) specified range

3 lots of CONTOUR NEXT blood glucose test strips was tested 10 times on each of 10 instruments for a total of 300 readings.

39 mg/dL to 348 mg/dL. With each blood specimen, each of

1.7 78.6 1.3 1.21-1.43 137.5 1.5 2.0 1.84-2.18 212.6 3.3 3.07-3.64 1.6 341.2 4.4 4.02 - 4.761.3

Principles of the Procedure: The Contour Next GEN blood

Table 2: System intermediate precision results for CONTOUR NEXT GEN meter using CONTOUR NEXT blood qlucose test strips 95% CI of SD, mg/dL

0.6

1.1

1.5

2.9

43.1

83.9

126.3

(FCC) Certified Device

4 219.9

5 370.6

0.56-0.66

0.98 - 1.17

1.41-1.67

2.64-3.12

6.5 6.04–7.15

1.4

1.3

1.2

1.3

1.8

Intermediate measurement precision (which includes variability

across multiple days) was evaluated using control solutions

at 5 glucose levels. With each control solution, each of 3 lots

300 readings. The following precision results were obtained.

each of 10 instruments on 10 separate days for a total of

of CONTOUR NEXT blood glucose test strips was tested once on

Federal Communications Commission

This equipment has been tested and found to meet 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 or more of the following measures:

Reorient or relocate the receiving antenna.

in the presence of other devices.

operate the device.

 Increase the separation between the equipment and receiver. This portable transmitter with its antenna complies with FCC RF exposure limits for general population/uncontrolled exposure. This device complies with part 15 of the FCC Rules. Operation is subject to the following 2 conditions: (1) This device may not cause harmful interference, and (2) this device must accept any

interference received, including interference that may cause Compliance with these guidelines means that under normal, daily circumstances, the device should not affect the operation of other devices. In addition, the device should operate normally

In the event there is interference from another device, it is recommended that you increase the distance between the meter and that device. You can also turn off the interfering device. In addition, you can turn off **Bluetooth** wireless technology on the meter. Changes or modifications to the device not expressly approved

by Ascensia Diabetes Care could void the user's authority to

If you have questions, contact Customer Service. See Contact

Countdown Time: 5 seconds **Memory:** Stores most recent 800 test results Battery Type: Two 3-volt CR2032 or DL2032 coin cell batteries, 225 mAh capacity

Meter Operating Humidity Range: 10% RH-93% RH **Test Strip Storage Conditions:** 41°F–86°F, 10%–80% Relative Humidity (RH)

Radio Frequency Band: 2.4 GHz-2.483 GHz Maximum Radio Transmitter Power: 1 mW Modulation: Gaussian Frequency Shift Keying (GFSK) Electromagnetic Compatibility (EMC): The CONTOUR NEXT GEN meter complies with the electromagnetic

Product Labeling Symbols The following symbols are used throughout the product system (meter packaging and labeling, and test strip and

The following symbols from the International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) are used throughout the product labeling for the CONTOUR NEXT GEN blood glucose monitoring system (meter packaging and labeling, and test strip and control solution packaging and labeling).

Indicates a carrier that ISO 15223-1, Clause 5.7.10 identifier information. identifier Indicates the manufacturer's catalog number so that ISO 15223-1. Catalog or the medical device can be Clause 5.1.6 identified. Indicates the date after which the medical device is Clause 5.1.4 Use-by date not to be used. ISO 15223-1 Indicates the Clause 5.1.5 manufacturer's batch code IEC 61010-2so that the medical device Batch Code 101, Table 1. can be identified. Symbol 102 IVD Indicates a medical device that is intended to be used ISO 15223-1, In Vitro as an in vitro diagnostic Clause 5.5.1 Diagnostic Indicates the temperature limits to which the medical ISO 15223-1, Clause 5.3.7 Temperature device can be safely limit

Graphic/Title		neierence
CONTROL	Indicates a control material that is intended to verify the performance characteristics of another medical device.	ISO 15223-1, Clause 5.5.2
Consult instructions for use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1, Clause 5.4.3
Caution: Read all warnings and precautions in instructions for use	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 15223-1, Clause 5.4.4 IEC 61010-1, Table 1, Symbol 14
Do not re-use	Indicates a medical device that is for single use or for use on a single patient during a single procedure.	ISO 15223-1, Clause 5.4.2
Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	ISO 15223-1, Clause 5.2.4

glucose test is based on measurement of electrical current caused by the reaction of the glucose with the reagents on the electrode of the test strip. The blood sample is drawn into the tip of the test strip through capillary action. Glucose in the sample reacts with FAD glucose dehydrogenase (FAD-GDH) and the mediator. Electrons are generated, producing a current that is proportional to the glucose in the sample. After the reaction time, the glucose concentration in the sample is displayed. No calculation by the user is required. Comparison Options: The CONTOUR NEXT GEN system is designed for use with capillary whole blood. Comparison with a laboratory method must be done simultaneously with aliquots of the same sample. NOTE: Glucose concentrations drop rapidly due to glycolysis (approximately 5%–7% per hour).9

References 1. US Food and Drug Administration. Use of fingerstick devices on more than one person poses risk for transmitting bloodborne pathogens: initial communication. US Department of Health and Human Services; update 11/29/2010. http:// wayback.archive-it.org/7993/20170111013014/http://www.fda. gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm 2. Centers for Disease Control and Prevention. Infection

Services; update June 8, 2017. http://www.cdc.gov/ injectionsafety/blood-glucose-monitoring.html 3. Wickham NWR, et al. Unreliability of capillary blood glucose in peripheral vascular disease. Practical Diabetes. 1986;3(2):100.

4. Atkin SH, et al. Fingerstick glucose determination in shock. Annals of Internal Medicine. 1991;114(12):1020-1024. **5.** American Diabetes Association. 2. Classification and diagnosis of diabetes: Standards of medical care in diabetes—2020.

6. International Organization for Standardization / Technical

Committee 210. Medical devices—Symbols to be used

with medical device labels, labelling and information to be

supplied—Part 1: General requirements. ISO 15223-1:2016.

Diabetes Care. 2020;43(supplement 1):S14-S31.

7. IEC 61010-2-101 Edition 3.0—Safety requirements for electrical equipment for measurement, control and laboratory use—Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment.

equipment for measurement, control, and laboratory use—

Clinical Chemistry. 5th edition. Philadelphia, PA: WB Saunders Co; 2001;444.

9. Burtis CA, Ashwood ER, editors. Tietz Fundamentals of

2) Mbed TLS: © The Mbed TLS Contributors https://www.trustedfirmware.org/projects/mbed-tls/

8. IEC 61010-1 Edition 3.1—Safety requirements for electrical

THE FOLLOWING SETS FORTH ATTRIBUTION NOTICES FOR THIRD-PARTY SOFTWARE THAT MAY BE CONTAINED IN PORTIONS OF THIS ASCENSIA PRODUCT.

1) Cortex Microcontroller Software Interface Standard (CMSIS): © ARM Limited https://developer.arm.com/tools-and-software/

contact Customer Service.

Test Sample: Capillary whole blood only Test Result: Referenced to plasma/serum glucose Sample Volume: 0.6 µL **Measuring Range:** 20 mg/dL–600 mg/dL of glucose in blood

Battery Life: Approximately 1000 tests (1 yr. average use, 3 tests per day) **Meter Operating Temperature Range:** 41°F–113°F **Control Testing Temperature Range:** 59°F–95°F

Dimensions: 78.5 mm (L) x 56 mm (W) x 18 mm (H) Weight: 53 grams **Meter Life:** 5 years with normal use in accordance with

Sound Output: 45 dB(A)-85 dB(A) at a distance of 10 cm

Radio Frequency Technology: Bluetooth Low Energy

requirements specified in IEC 60601-1-2 Edition 4.0. Electromagnetic emissions are low and unlikely to interfere

labeling for the CONTOUR NEXT GEN blood glucose monitoring

Unique device | contains unique device with other nearby electronic equipment, nor are emissions from nearby electronic equipment likely to interfere with the model number CONTOUR NEXT GEN meter. control solution packaging and labeling). Symbol What It Means Control Discard Date Shake 15 times Medical Device | medical device.

Prevention during Blood Glucose Monitoring and Insulin License 2.0 available at https://www.apache.org/licenses/ Administration. US Department of Health and Human

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Part 1: General requirements.

Third Party Notices

November 28, 2024 4:47 PM

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