

microdot[®] **PRO**

Blood Glucose Monitoring System

OPERATIONS & QUALITY ASSURANCE PROCEDURE MANUAL



USE ONLY WITH



microdot[®] **PRO** Test Strips

For use by
Health Care Professionals

CS[®]

CAMBRIDGE SENSORS USA, LLC

TABLE OF CONTENTS

Chapter	Page
1. microdot® PRO Meter Overview & System Components	2-5
2. Initial Setup of the microdot® PRO Meter	6-14
3. Control Solution Testing	15-18
4. Testing with Patients	19-22
5. microdot® PRO Meter Specifications	23
6. In-Service Training Outcomes	24
7. microdot® PRO Blood Glucose Meter Log Sheets	26-29
7A. microdot® PRO In-Service Form	26
7B. microdot® PRO Qualified Trainers Form	27
7C. microdot® PRO Qualified Trainer/Operator Certification Form	28
7D. microdot® PRO Quality Control Record	29
8. Material Safety Data Sheets	30-47
8A. microdot® PRO Test Strips	30-32
8B. microdot® PRO Control Solutions	33-35
8C. microdot® Bleach Wipe	36-39
8D. microdot® Minute Wipe	40-47
9. Troubleshooting the microdot® PRO Meter	48
10. microdot® PRO Meter Quick Start Videos	49
11. Manufacturer's Cleaning Instructions	50
12. microdot® PRO Meter Limitations	51
13. Notes	52

Chapter 1

microdot[®] PRO BLOOD GLUCOSE METER OVERVIEW

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This section provides general information on the microdot[®] PRO Glucose Monitoring System

The microdot[®] PRO Blood Glucose Monitoring System is a portable whole blood testing system which performs tests with quick and accurate results.

It consists of three main parts:

1. microdot[®] PRO Blood Glucose Meter
2. microdot[®] PRO Test Strips
3. microdot[®] PRO Level 1 and Level 3 Control Solutions

These products have been designed, tested and proven to work together as a system to produce safe and accurate results. **Use only microdot[®] PRO Test Strips and Control Solutions with the microdot[®] PRO Glucose Meter.**

System includes:

microdot[®] PRO Meter
Protective Orange Meter Sleeve
Quality Assurance Manual
Lifetime Warranty
Two 3V Lithium Batteries (installed)

Additional components include:

microdot[®] PRO Test Strips
microdot[®] PRO Level 1 and Level 3 Control Solutions

INTENDED USE

The microdot[®] PRO Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in venous whole blood, or capillary whole blood drawn from the fingertips, forearm, or palm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). Testing is done outside the body (in vitro diagnostic use). It is intended for multiple-patient use in professional healthcare settings. This system should only be used with single use, auto-disabling lancing devices. It is not indicated for the diagnosis of or screening for diabetes or for neonatal use.

Users need to adhere to Standard Precautions when handling or using this device. All parts of this glucose monitoring system should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and healthcare professionals. The meter should be disinfected after use on each patient.

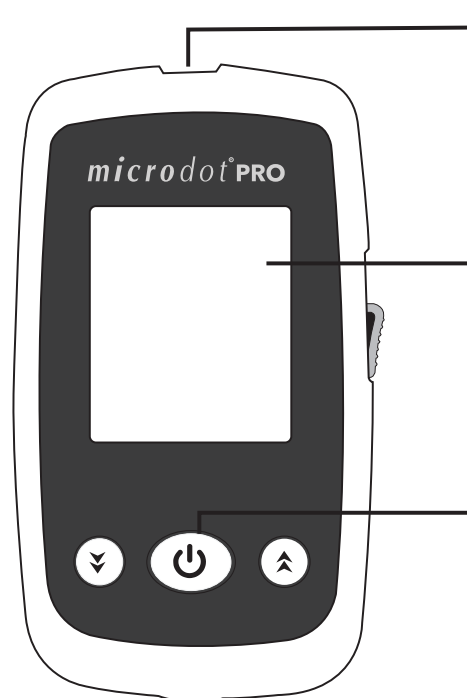
NOTE:

- microdot[®] Safety Lancets are available for purchase separately.
- microdot[®] PRO Blood Glucose Test Strip (vial or foil-wrapped) and microdot[®] PRO Glucose Control Solution are necessary but sold separately.

Please call our toll free number at: 1.877.374.4062 Monday through Friday from 9am to 5pm CST for purchasing information.

SYSTEM COMPONENTS

microdot[®] PRO METER



Test Strip Port

This is where you insert the test strip and the meter will turn on automatically.

Meter Display

Shows blood glucose test results, memory values, and other messages.

Enter (⏻) and ▲ ▼ buttons

Press and hold Enter (⏻) for 2 seconds to turn the meter on or off, or press Enter (⏻) to go into setup mode when not testing.

Press ▲ or ▼ to enter control mode with test strip inserted, during meter setup, or to navigate the stored test values.

Ejection Switch

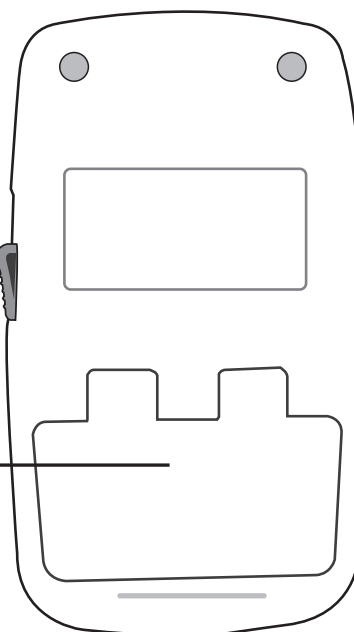
Push and eject a used test strip. Meter will turn off automatically when the test strip is ejected.

Battery Compartment

Holds two CR 2032 3V Lithium coin cell batteries.

Data Port

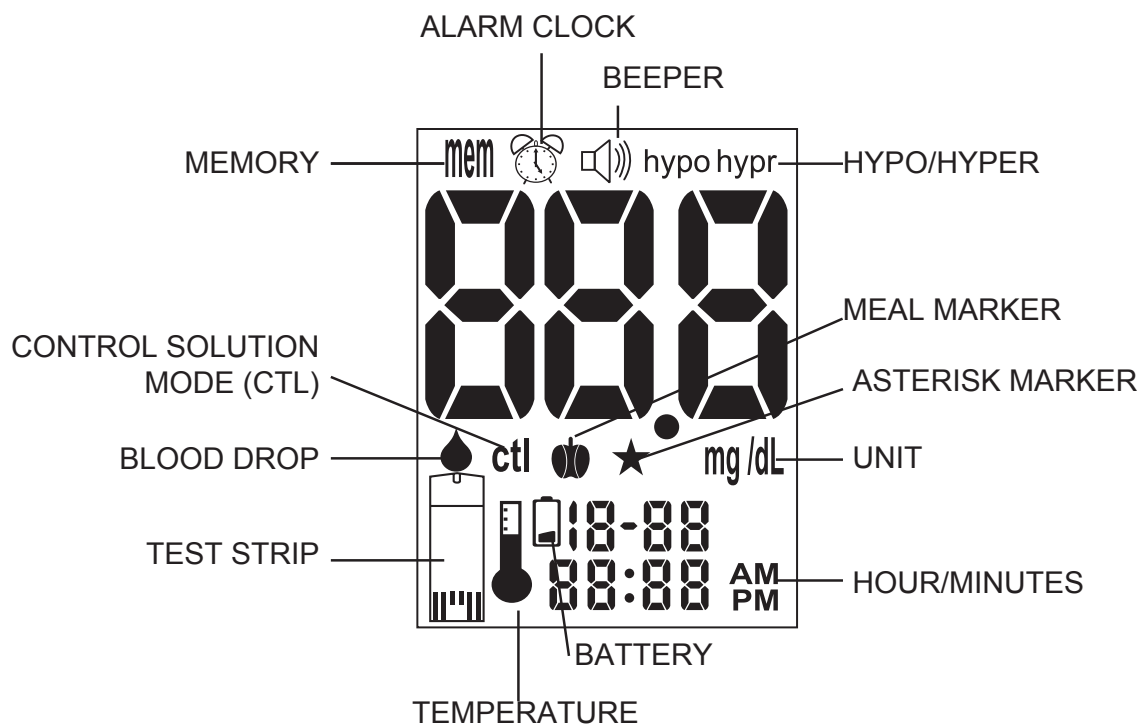
Transmits data to computer.



SYSTEM COMPONENTS

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microdot[®] PRO METER DISPLAY SCREEN

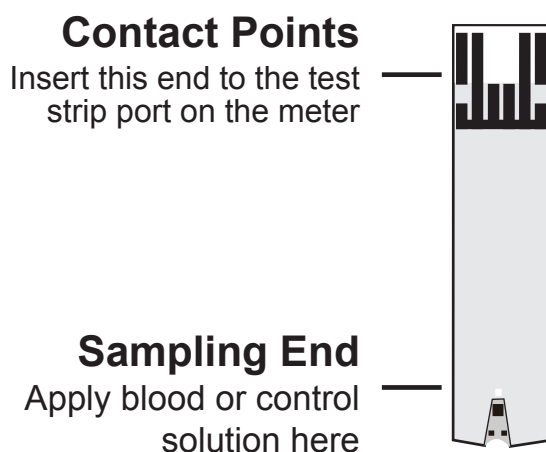


SYSTEM COMPONENTS

microdot[®] PRO TEST STRIPS

The microdot[®] PRO Blood Glucose Test Strip is a glucose specific, biosensor-based test strip that can test glucose in in capillary or venous whole blood in as quickly as 8 seconds and requires very little blood sample. The test result is plasma referenced for easy comparison to lab results and has under-fill detection to alert you when there is not enough blood to perform a test, so you can be confident that each reading you get is an accurate result.

The microdot[®] PRO Test Strip consists of the following parts:

**IMPORTANT:**

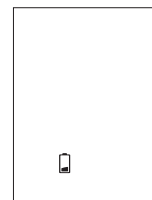
- Be sure to use only the microdot[®] PRO Blood Glucose Test Strip with the microdot[®] PRO Meter. Other brands of test strips will not work with the meter.
- The microdot[®] PRO Blood Glucose Test Strip is sensitive to moisture and light. For vial test strip, it is important to close the vial cap of the test strip bottle tightly after each use. DO NOT leave any test strips outside the bottle while not in use. For foil-wrapped test strip, DO NOT open the foil wrapping until performing tests.
- Carefully discard used test strips and lancets in proper waste containers.
- DO NOT reuse test strips. Test strip is for single use only.

INITIAL SET UP *microdot*[®] PRO METER

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INSERTING (OR CHANGING) THE BATTERIES

The batteries need to be inserted before using your microdot[®] PRO Meter for the first time or when the “” icon appears on the meter display.

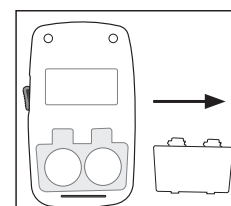


Material you will need:

- Two CR 2032 3V Lithium coin cell batteries
- microdot[®] PRO Meter

Step 1.

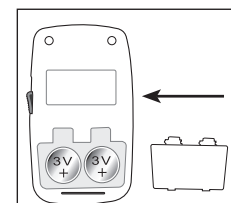
Turn the meter off. Remove the battery cover on the back of the meter by pushing the tab and pulling the door up. Remove the old batteries.



Step 2.

Insert the new batteries with the + side up. They do not snap into place but rest on the metal contact. The door holds the batteries down.

Put the battery door back in place and snap it closed.



NOTE:

- After changing the batteries, the meter automatically prompts you to check the time and date when it is turned on either by inserting a test strip or pressing “”. If it is correct, press “” to confirm setup and exit, or if the time and date are not correct, turn to page 7 for Setting the Clock.
- The date and stored results will not be erased when the batteries are being changed.
- Discard used batteries according to your local regulations.
- The meter uses two 3-volt lithium batteries, coin cell CR2032. This type of battery can be found in many stores. Always keep spare packaged batteries on hand.
- Be sure the batteries go in + side up.
- Remove the batteries if unused for a long time.

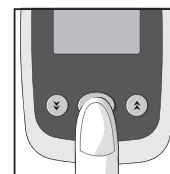
INITIAL SET UP *microdot*[®] PRO METER

SETTING THE CLOCK

Material you will need: microdot[®] PRO Meter

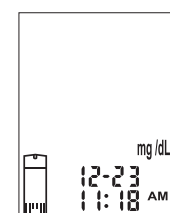
Step 1.

Press and hold “⏻” to turn on the meter.



Step 2.

The flashing test strip icon will appear on the meter display screen.



Step 3.

Press “▲” twice until meter display screen shows “🕒”.



Set Year

Step 4.

Press “⏻” and the current year will flash. Use “▲” or “▼” to select the correct year.

Press “⏻” to confirm your choice and advance to set the month.

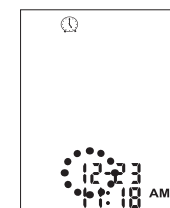


Set Month

Step 5.

The current month will flash. Use “▲” or “▼” to select the correct month.

Press “⏻” to confirm your choice and advance to set the day.

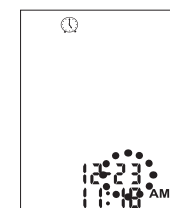


Set Day

Step 6.

The current day will flash. Use “▲” or “▼” to select the correct day.

Press “⏻” to confirm your choice and advance to set the 12-hour or 24-hour time format.



Chapter 2

INITIAL SET UP *microdot*[®] PRO METER

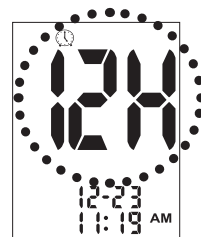
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SET 12-HOUR OR 24-HOUR TIME FORMAT

Step 7.

The time format will flash. Use “▲” or “▼” to select the time format of your choice.

Press “⏻” to confirm your choice and advance to set the hour.

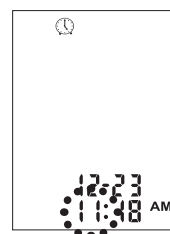


Set Hour

Step 8.

The current hour will flash. Use “▲” or “▼” to select the correct hour.

Press “⏻” to confirm your choice and advance to set the minutes.

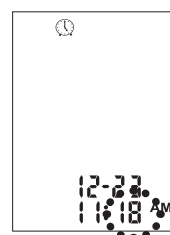


Set Minutes

Step 9.

The current minutes will flash. Use “▲” or “▼” to select the correct minutes.

Press “⏻” to confirm your choice and exit time setup.



NOTE:

- Anytime during setup, you may either press “⏻” to exit, or insert a microdot[®] PRO Blood Glucose Test Strip to begin testing. The changes you have done so far will be memorized by the meter.

After setting up the clock, you can turn off the meter by holding and pressing “⏻”, continue to set the meter, or insert a test strip to begin testing (see Testing Blood Glucose on page 19 or Control Solution Testing on page 15).

INITIAL SET UP *microdot*[®] PRO METER

SETTING THE ALARM

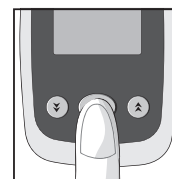
You can set up to three alarms on the microdot[®] PRO Meter. You must set the clock before setting the alarms. When an alarm rings, a melody will play for 30 seconds. Pressing “⏻” or inserting a test strip will silence the alarm.

Materials you need:

- microdot[®] PRO Meter

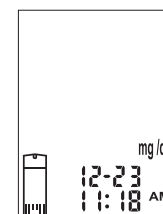
Step 1.

Press and hold “⏻” to turn on the meter.



Step 2.

The flashing test strip icon will appear on the meter display screen.



Step 3.

Press "▲" or "▼" until “🕒” starts to flash. Press “⏻” to enter alarm setting.



Step 4.

The display screen will indicate alarm 1 status (the default is OFF). You can turn it on by pressing "▲" or "▼". Press “⏻” to confirm your choice and advance to set hours.



Step 5.

The hours will flash. Press "▲" or "▼" to select the hour. Press “⏻” to confirm your choice and advance to set minutes.



Chapter 2

INITIAL SET UP *microdot*[®] PRO METER

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SETTING THE ALARM

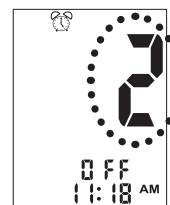
Step 6.

The minutes will flash. Press "▲" or "▼" to select the correct minutes. Press "⏻" to confirm your choice and advance to set alarm 2.



Step 7.

Set alarm 2 and 3 by following steps 4 through 6. After you have finished setting up alarm 3, press "⏻" to exit alarm setup.



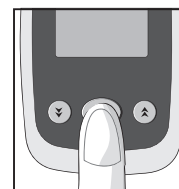
NOTE:

- Alarm will follow the time format (12-hour or 24-hour) you chose when setting up the clock.
- Alarm settings will not be erased when changing batteries.

INITIAL SET UP *microdot*[®] PRO METER

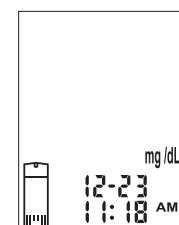
TURNING ON/OFF TONE SOUND

The microdot[®] PRO Meter comes with the sound ON as preset. The beeper will sound once to remind you when turning on/off the meter, applying samples, or ending countdown. You will get two beep sounds warning if the results show “hypo”, “hypr”, “HI” or “LO”.



Step 1.

Press and hold “” to turn on the meter.



Step 2.

The flashing test strip icon will appear on the meter display screen.



Step 3.

Press “” or “” until meter display screen shows “”.

Step 4.

Press “” to enter tone setting. Use “” or “” to turn on/off the tone.



Step 5.

Press “” to exit once you have made your selection.

NOTE:

- Anytime during setup, you may either press “” to exit, or insert a microdot[®] PRO Blood Glucose Test Strip to begin testing. The changes you have done so far will be memorized by the meter.

Begin testing by inserting a microdot[®] PRO Blood Glucose Test Strip (see Testing Blood Glucose on page 19 or Control Solution Testing on page 15), or press and hold “” to turn off the meter.

INITIAL SET UP *microdot*[®] PRO METER

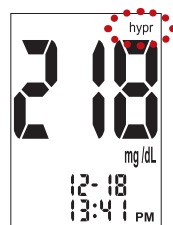
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SETTING WARNING VALUES

The microdot[®] PRO Meter has a feature to set a high and low blood glucose threshold (hyperglycemia and hypoglycemia values). Based on the values set up, the LCD screen will show “hypo” if the blood glucose test result is below the low glucose threshold value (hypoglycemia level), or the LCD screen will show “hypr” if the blood glucose test result is above the high glucose threshold value (hyperglycemia level).



HYPO (hypoglycemia)



HYPER (hyperglycemia) warning

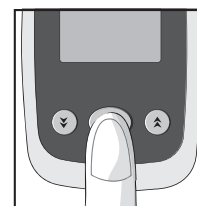
The factory preset threshold value is 70 mg/dL for hypo and 250 mg/dL for hyper. The allowable range of the threshold setting is 20 to 130 mg/dL for hypo and 100 to 600 mg/dL for hyper, but the hyper value will never be lower than the hypo value. Follow the steps below to adjust the hypo and hyper threshold values.

Material you will need:

- microdot[®] PRO Meter

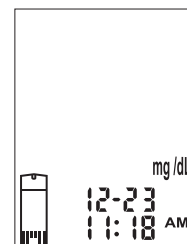
Step 1.

Press and hold “” to turn on the meter.



Step 2.

The flashing test strip icon will appear on the meter display screen.



INITIAL SET UP *microdot*[®] PRO METER

Setting up hypo (hypoglycemia) warning value

Step 3.

Press “▲” or “▼” until the meter display screen shows “hypo”.

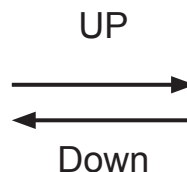
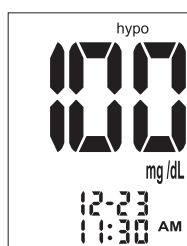
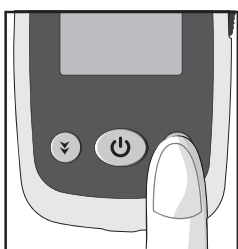
Step 4.

Press “⏻” to enter hypo setup.



Step 5.

Press “▲” or “▼” to select the desired value. Press and hold either “▲” or “▼” will accelerate numbering. Press “⏻” to confirm and exit hypo setup. You will return to the meter display screen.



Step 6.

Press “▲” or “▼” until the main display screen shows “hypr”.

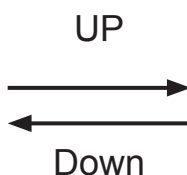
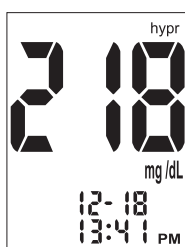
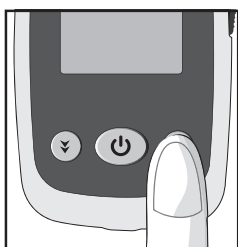
Step 7.

Press “⏻” to enter hyper setup.



Step 8.

Press “▲” or “▼” to select the desired value. Press and hold either “▲” or “▼” will accelerate numbering. Press “⏻” to confirm and exit hyper setup. You will return to meter display screen.



Chapter 2

INITIAL SET UP *microdot*[®] PRO METER

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ENABLE/DISABLE QC LOCK MODE

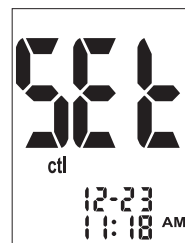
The microdot[®] PRO Meter offers you a choice to set the device in the QC lock mode. When the QC lock mode is on and no control test has been performed in the past 24 hours, the message “qC” will flash on the screen and you will need to perform control tests before running a glucose test.

Materials you will need:

- microdot[®] PRO Meter

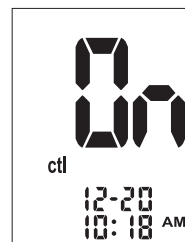
Step 1.

Press and hold “⏻” to turn on the meter.



Step 2.

Press “▼” down once until the meter display screen shows “ctl”.



Step 3.

Press “⏻” to enter QC lock setting. Use “▲” or “▼” to turn on/off QC lock.

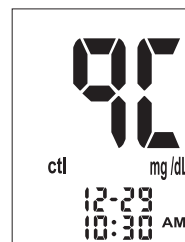
Step 4.

Press “⏻” to confirm and exit QC lock setup. You will return to the meter display screen.

Begin testing by inserting a microdot[®] PRO Blood Glucose Test Strip (see Testing Your Blood Glucose on page 19 or Control Solution Testing on page 15), or press and hold “⏻” to turn off the meter.

If the QC lock is on and no control test has been executed in the past 24 hours, the screen will show the flashing message “qC” when you insert a test strip. You will not be able to run glucose tests without running a control test first.

Press “▼” to select control level (L1, L2 or L3), see Control Solution Testing on page 16 for detail steps.



CONTROL SOLUTION TESTING

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PERFORMING A CONTROL SOLUTION TEST

The purpose of the control solution testing is to validate the performance of the microdot[®] PRO Blood Glucose Monitoring System using the testing solution with a known range of glucose. Control solutions are necessary but sold separately. Please call our toll free number at: 1.877.374.4062 Monday through Friday from 9am to 5pm CST for purchasing information.

You should perform control solution testing when:

- Using the meter for the first time
- You open a new package of microdot[®] PRO Blood Glucose Test Strips
- You leave the cap of the test strip vial open for a while
- You drop the meter
- You suspect your microdot[®] PRO Meter and microdot[®] PRO Blood Glucose Test Strip are not working properly
- The blood glucose test results do not reflect patient symptoms
- You want to practice the testing procedure

IMPORTANT:

- Use only the microdot[®] PRO Glucose Control Solution (Level 1 and Level 3) with the microdot[®] PRO Blood Glucose Test Strip. Other brands of control solution will produce inaccurate results.
- Always check the expiration date. DO NOT use control solutions if expired.
- Mark the newly opened bottle of control solution with the date opened. Discard any unused control solution three months after opening.
- DO NOT FREEZE or REFRIGERATE. Store the control solutions at 39°F~86°F.

CONTROL SOLUTION TESTING

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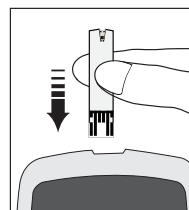
PERFORMING A CONTROL SOLUTION TEST

Materials you will need:

- microdot[®] PRO Glucose Control Solution (Level 1 and Level 3)
- microdot[®] PRO Meter
- New microdot[®] PRO Blood Glucose Test Strips

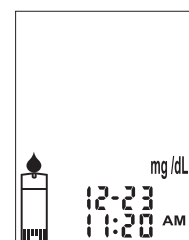
Step 1.

Insert a microdot[®] PRO Blood Glucose Test Strip into the meter with the blood sample reaction zone facing up. Make sure the test strip contact points are inserted all the way into the meter.



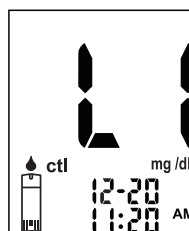
Step 2.

Wait until the flashing blood drop and test strip icons appear on the lower left of the meter display screen.



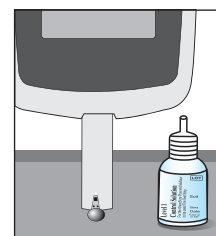
Step 3.

Press “▼” to enter the control mode. You will see “ctl” on the lower left of the screen. Use “▲” or “▼” to select control level (L1, L2 or L3).



Step 4.

Squeeze a drop of control solution (Level 1, or Level 3) on the top of the control solution cap. Do not apply control solution to the test strip directly from the control vials. Note- if test strip enzyme leaches into control solution vials (level 1 and 3), control solutions could become contaminated and not work properly.



Step 5.

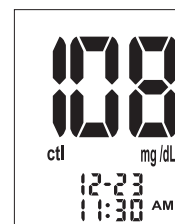
Hold the meter and touch the control solution to the edge of the sampling end of the test strip. The control solution will be automatically pulled into the reaction area of the test strip.

CONTROL SOLUTION TESTING

Step 6.

The screen will begin to count down. After 8 seconds, the control solution testing result will appear on the meter display screen.

A “ctl” flag will also be attached when results are shown on the screen.



Step 7.

Compare the reading on the screen to the control range printed on the test strip bottle (for vial test strip) or box (for foil-wrapped test strip). If the reading does not fall within the control range printed on the test strip bottle or box, see Control Solution Trouble Shooting on page 18.

Level 1:	43-73
Level 2:	108-135
Level 3:	194-239

* example control ranges

NOTE:

- Control solution testing results will be stored into the meter's memory and indicated by “ctl” icon.
- Different bottles or boxes of the test strip may have different control range.

Step 8.

Remove the used test strip either by pushing the ejection switch or by pulling it out with your hand and discard into a proper biohazard container.

Insert a new test strip to perform the next test, or press and hold “⏻” to turn off the meter.

IMPORTANT:

- Do not reuse test strips.
- Do not use a test strip that has expired. Check the expiration date which is printed on the test strip bottle (for vial test strip) or box (for foil-wrapped test strip).
- Use each test strip immediately after removing it from the bottle or opening a foil wrapping.
- For vial test strip, replace the bottle cap immediately and close it tightly after removing a test strip from the bottle.
- Do not use wet, bent or damaged test strips.
- Keep away from direct sunlight and heat. Store the test strip in a dry, cool place.
- For vial test strip, record the “date opened” on the test strip bottle label when you first open it. Six months after first opened, discard the bottle and any remaining test strips.
- For foil-wrapped test strip, do not use scissors to open the foil wrapping. Scissors can damage test strips.
- Make sure you are testing in an environment between 41°F~113°F and 20~90% RH, and allow 10 to 15 minutes for it to reach the new temperature before use. Your meter will not begin testing if it detects an out-of-range temperature.
- This is an auto-coding meter. You do not need to insert a code card.
- Must see a flashing blood drop icon if the test strip has been inserted to the test strip port.

Perform other levels of control solution testing by repeating the above steps.

CONTROL SOLUTION TESTING

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CONTROL SOLUTION TROUBLE SHOOTING

If your control solution testing is out of range (too low or too high), it may be caused by the following:

Possible Causes	What you can do ...
• Wrong brand of control solution being used	• Make sure you are using microdot® PRO Glucose Control Solution (Level 1 and Level 3).
• Control solution not at room temperature	• Make sure the testing environment is between 41°F~113°F and 20~90% RH.
• Expired, used or contaminated control solution or damaged test strips	• Check the expiration and opened date on bottles of both control solution and test strips. Repeat the test using a new test strip. If the result is still out of range, use a new bottle of control solution and retest.
• Meter malfunction	• Please call our toll free number at: 1.877.374.4062 Monday through Friday from 9am to 5pm CST for questions and inquiries.

TESTING WITH PATIENTS

TESTING BLOOD GLUCOSE LEVELS

Materials you will need:

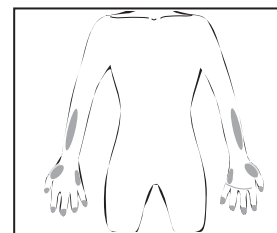
- microdot[®] PRO Meter
- A new microdot[®] PRO Blood Glucose Test Strip
- Safety Lancet
- Clear cap for Alternative Site Testing (AST) on palm and forearm

Before you begin, make sure:

- To set up the meter properly and run a control test. See Initial Setup on page 6 and Control Solution Testing on page 15 for more details.
- To prepare patient test site with an alcohol prep pad.
- You are testing in an area between the temperature ranges of 41°F~113°F and relative humidity ranges of 20~90%. The meter will not test outside of this range and will display “”. Move the meter into an area that is between 41°F~113°F and 20~90% RH, and let it sit for 10 to 15 minutes before testing again.

IMPORTANT INFORMATION ON ALTERNATIVE SITE TESTING (AST)

The microdot[®] PRO Blood Glucose Monitoring System can test for blood glucose from two sites other than the fingertip. These alternative sites are the palm and forearm (alternative site testing, or AST). Alternative site testing can be less painful than fingertip testing, but because of the physiological difference between your fingertip and palm and forearm⁽¹⁾, AST result may be significantly different than results from fingertip testing under certain conditions.



Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly).

Alternative site measurements should never be used to calibrate continuous glucose monitors (CGMs).

Alternative site measurements should never be used for insulin dosing calculations.

TESTING WITH PATIENTS

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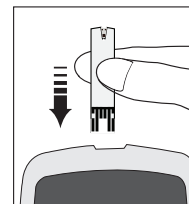
PERFORMING A BLOOD GLUCOSE TEST

Step 1.

Insert a test strip to turn on the meter.

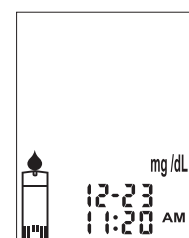
TIP:

- Insert until strip bottoms out, or hits back of meter. Full Insert.



Step 2.

Wait until the flashing blood drop and test strip icons appear on the lower left of the meter display screen.

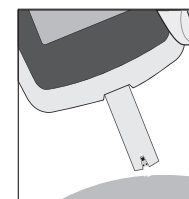


Step 3.

Obtain blood sample.

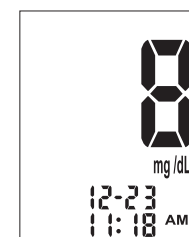
Step 4.

Must see the flashing blood drop icon before applying blood. Gently bring the test strip and touch the drop of blood at a slight angle. The test strip acts like a straw to pull the blood in. Keep the test strip in the blood drop until the meter beeps to indicate the test strip has enough blood to test.



Step 5.

The screen will start to count down. After count down, the glucose test result will appear on the meter display screen.



IMPORTANT:

- Check the expiration date printed on the test strip bottle (for vial test strip) or box (for foil-wrapped test strip). Do not use expired test strips.
- Use each test strip immediately after removing it from the bottle or opening a foil wrapping.
- Do not use wet, bent or damaged test strips.
- Keep away from direct sunlight and heat. Store the test strips in a dry, cool place.
- For vial test strip, record the "date opened" on the bottle label. Discard the bottle and any remaining test strips after six months from date of opening.
- For foil-wrapped test strips, do not use scissors to open the foil wrapping. Scissors can damage test strips.
- Insufficient blood sample may cause incorrect results.
- Must see a flashing blood drop icon if the test strip has been inserted to the test strip port.

TESTING WITH PATIENTS

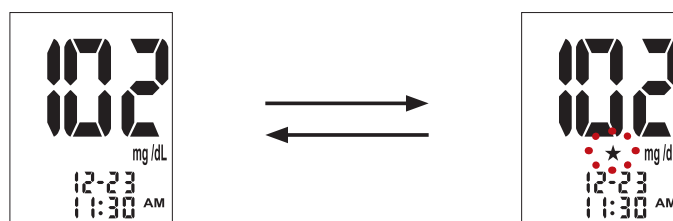
Step 6: Select the before/after meal marker

With the test result on the display, and the test strip still in the meter, press either “▲” or “▼” to select  for before meal,  for after meal, or blank if the test result does not apply. Press “⏻” to confirm your choice and advance to select asterisk marker.



Step 7: Select the asterisk marker

After selecting meal state, a flashing “★” icon appears in the middle of the screen. You can mark your result to remind you an event such as an AST result or exercise. Use “▲” or “▼” to turn the option on/off, and press “⏻” to confirm your choice. The result will be stored in memory.



The test result will be stored without markers if the strip is removed without selection.

Step 8.

Remove the used test strip either by pushing the ejection switch or by pulling it out with gloved hand and discard into a proper biohazard bag or container.

CAUTION:

- If you see “HI” or “LO” is displayed, the blood glucose level may be beyond the meter's measurement range (above 600 mg/dL or below 20 mg/dL). Test again using fingertip testing, DO NOT test on palm or forearm.

NOTE:

- “hypo” or “hypr” icons may appear on screen depending on the threshold limit you have set up. Refer to Setting Warning Values on page 12.
- Follow the instructions (Page 50) for how to clean and disinfect the microdot® PRO Meter.

TESTING WITH PATIENTS

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UNDERSTANDING BLOOD GLUCOSE TEST RESULTS

Blood glucose values will vary depending on food intake, medication, health, stress, and exercise. The ideal ranges for adults without diabetes are⁽²⁾:

- less than 100 mg/dL before meals.
- less than 140 mg/dL two hours after meals.

IMPORTANT:

- Inaccurate results may occur in severely hypotensive individuals or patients in shock.
- Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis.
- Critically ill patients should not be tested with this device.

2. American Diabetes Association, Standards of Medical Care in Diabetes—2016. Diabetes Care, Vol.39, Supplement 1, p. S16, table 2.3.

microdot[®] PRO SPECIFICATIONS

Test Strips:	microdot [®] PRO Blood Glucose Test Strip
Test Range:	20~600 mg/dL
Calibration:	Plasma
Blood Sample Size:	Minimum 0.8 μ L
Hematocrit Range:	10~70%
Event management:	Before/After meal marker and asterisk marker
Warnings:	User configurable hypoglycemia and hyperglycemia warnings, underfill warning
Display Type:	LCD screen with back lighting
Memory:	1000 test results with date and time
Dimensions:	105L x 60W x 14.5H (mm)
Weight:	51g (without batteries)
Battery:	2 x CR 2032 3V Lithium coin cell batteries
Battery Life:	1000 tests of continuous use or one year
Automatic Power-Off:	After 2 minutes inactivity
Operating Temperature:	41°F~113°F
Operating RH%:	20~90%
Alarms:	3
Storage/Transport Condition:	Meter at -4°F~122°F, <93% RH Test Strips at 39°F~86°F, 10~85% RH

Chapter 6

IN-SERVICE TRAINING OUTCOMES

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Once your microdot® PRO Meter in-service is complete, Health Care Professionals should be able to:

1. Locate and explain the following components of the microdot® PRO Meter:

Eject Button
Test Strip Port
Battery Compartment
Serial Number
Customer Service Number

2. Locate and explain the label information on the microdot® PRO Meter Test Strip Vial:

Discard Date
Lot Number
Expiration Date
Control Ranges
Storage Temperature Range

3. Set Time and Date of Meter

4. Identify three parts of the microdot® PRO Meter Test Strips

Top Edge
Test Pad
Contact Bars

5. Identify the following parts of the microdot® PRO Meter Control Solution Bottles:

Low vs. High
Discard Date
Lot Number
Expiration Date
Storage Temperature Range

6. Properly insert the microdot® PRO Meter Test Strip

7. Perform control solution tests

8. Document and maintain microdot® PRO Quality Control Records

9. Obtain a blood sample

10. Perform a blood test

11. Identify meter result range

12. Access meter memory

13. Change the battery

14. Identify and resolve error readings

microdot[®] **PRO**

BLOOD GLUCOSE MONITORING SYSTEM LOG SHEETS

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The forms in this chapter are Master Copies.
Please make photocopies for distribution.
If you need replacement documents, please
contact Customer Service at: **877.374.4062**

microdot[®]**PRO**
BLOOD GLUCOSE MONITORING SYSTEM IN SERVICE FORM
.....

The Health Care professionals listed below are trained and have demonstrated proficiency using the microdot[®] PRO Blood Glucose Monitoring System.

Cambridge Sensors Representative/Qualified Trainer

Date	Health Care Professional's Name

The chart is designed for use during the initial training on the microdot[®] PRO Blood Glucose System by a Cambridge Sensors Representative, In-Service Video or Qualified Trainer

***microdot*[®] PRO BLOOD GLUCOSE MONITORING SYSTEM**
QUALIFIED TRAINERS FORM

[illegible]

Cambridge Sensors Representative

Cambridge Sensors Representative Signature

Date _____

microdot[®] PRO BLOOD GLUCOSE MONITORING SYSTEM QUALIFIED TRAINERS FORM

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I. microdot[®] PRO Meter - Locate the following:

- a. Battery
- b. Serial Number
- c. Toll Free Customer Service Number
- d. Eject Button

II. Identify and explain the following:

- a. Blood Test Procedure
- b. Control Solution Procedure
- c. Troubleshooting

III. Explain proper procedure for:

- a. Dating of microdot[®] PRO Test Strips and Control Solution
- b. When to perform a Control Test
- c. Handling Control Solution results that are out of range

IV. Perform and explain the following procedures:

- a. Control Solution testing
- b. Blood testing
- c. Recalling test results
- d. Changing the battery

If all tasks were not properly completed, have the operator repeat the procedure correctly. When all tasks have been properly completed, sign bottom of this form and fill out the proper Qualified Trainer or In-service form.

Cambridge Sensors USA Sales Rep.

Date

Qualified Trainer

Date

Operator

Date

***microdot*[®] PRO BLOOD GLUCOSE MONITORING SYSTEM**
QUALIFIED TRAINERS FORM

microdot® PRO Meter Serial Number _____

Month/Year _____

[illegible]

SAFETY DATA SHEETS

microdot® PRO Blood Glucose Test Strips

According to EC Directive 91/155/EEC

1. Identification of the substance/preparation and of the company/undertaking

Identification of the product

Product name: **microdot PRO Blood Glucose Test Strip**

Manufacturer identification

Company: **APEX BIOTECHNOLOGY CORP.**

Address: No. 7, Li-Hsin Rd. V, Hsinchu Science Park, Hsinchu, Taiwan, R.O.C

Telephone: 886-3-5641952

Fax: 886-3-5678302

2. Composition/information on ingredients

Chemical composition (for test strip's reaction zone per cm²):

Ingredients	Supplier	Concentration (% w/w)
[FAD] Glucose Dehydrogenase	Amano	13.14 % w/w
Electron Shuttle	MERCK	38.16% w/w
Non-reactive ingredients (included enzyme protector)	MERCK & SIGMA	48.7% w/w

3. Hazards identification

No suitable data for toxicological evaluation are available. We are not aware of any hazards for the above product. The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. In this context, hazardous properties can therefore not be excluded. APEX BIOTECHNOLOGY CORP. shall not be held liable for any damage resulting from handling or from contact with the above product.

4. First-aid measures

General information:

After inhalation: Not likely to occur

After skin contact: Wash off under running water

After eye contact: Flush with water

After swallowing: Not likely to occur

SAFETY DATA SHEETS

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 microdot® PRO Blood Glucose Test Strips

5. Fire-fighting measures Extinguishing media: CO ₂ , Foam, Dry chemical Unsuitable extinguishing media: none Special hazards: none Special protective equipment for fire fighting: Do not stay in dangerous zone without self-contained breathing apparatus.
6. Accidental release measures Person-related precautionary measures: Store away from light, heat and open flames. Environmental precautions: Observe local by-laws. Methods for cleaning up: In accordance with national/local regulations relating to biological waste disposal.
7. Handling and storage Handling: Follow instructions for use Storage: • Store at temperatures between 39°F-86°F (4°C-30°C) • Store away from direct sunlight
8. Exposure controls/personal protection General: None
9. Physical and chemical properties Appearance: Thin plastic sheets with applied chemicals and desiccant bead. Odor: odorless pH: Not applicable Solubility in water: Not soluble Physical characteristics: Not significant

SAFETY DATA SHEETS

microdot® PRO Blood Glucose Test Strips

10. Stability and reactivity Conditions to avoid: moisture and light Hazardous decomposition products: None
11. Toxicological information Acute toxicity: Not testing Chronic effects of overexposure: None currently known Inhalation, skin contact and eye contact: Not considered health risks
12. Ecological information Ecological effects: None determined
13. Disposal considerations Product: microdot PRO Blood Glucose Test Strips, before or after used, must be disposed of in compliance with the respective regulations. Packaging: product packaging must be disposed of in compliance with the country-specific regulations or must be passed to a packaging return system.
14. Transport information This product is not classified as dangerous for transport. Not restricted according to IATA & DGR regulation.
15. Regulatory information Not hazardous
16. Other information None

Review Date: 2025/02/03

SAFETY DATA SHEETS

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microdot® PRO Control Solutions

According to EC Directive 91/155/EEC

1. Identification of the substance/preparation and of the company/undertaking

Identification of the product

Product name: **microdot® PRO Glucose Control Solution**

Manufacturer identification

Company: **APEX BIOTECHNOLOGY CORP.**

Address: No. 7, Li-Hsin Rd. V, Hsinchu Science Park, Hsinchu, Taiwan, R.O.C.

Telephone: 886-3-5641952

Fax: 886-3-5678302

2. Composition/information on ingredients

Chemical composition (for three levels of the microdot PRO Glucose Control Solution):

Ingredients	Supplier	Concentration (% w/v)
Glucose for Level 1	Merck (CAS 50-99-7)	0.06%
Level 3		0.16%
Preservative	Merck (CAS 532-32-1)	1.00%
New Coccine	Daiwa (CAS 2611-82-7)	0.10%
Non-reactive ingredients for Level 1	Sigma (CAS 9003-39-8)	10%
Level 3		10%
The remainder composition not enough to 100% is water.		

3. Hazards identification

No suitable data for toxicological evaluation are available. We are not aware of any hazards for the above product. The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. In this context, hazardous properties can therefore not be excluded. APEX BIOTECHNOLOGY CORP. shall not be held liable for any damage resulting from handling or from contact with the above product.

SAFETY DATA SHEETS

microdot® PRO Control Solutions

4. First-aid measures

General information:

After inhalation: Not likely to occur

After skin contact: Wash off under running water

After eye contact: Flush with water

After swallowing: Not likely to occur

5. Fire-fighting measures

Extinguishing media: CO₂, Foam, Dry chemical

Unsuitable extinguishing media: none

Special hazards: none

Special protective equipment for fire fighting: Do not stay in dangerous zone without self-contained breathing apparatus.

6. Accidental release measures

Person-related precautionary measures: Store away from light, heat and open flames.

Environmental precautions: Observe local by-laws.

Methods for cleaning up: In accordance with national/local regulations relating to biological waste disposal.

7. Handling and storage

Handling: Follow instructions for use

Storage:

- Store at temperatures between 39°F-86°F (4°C-30°C)
- Store away from direct sunlight

8. Exposure controls/personal protection

General: None

9. Physical and chemical properties

Appearance: plastic bottle

Odor: odorless

pH: requirement to maintain specific range

Solubility in water: Yes

Physical characteristics: Not significant

Product state: Liquid

Flash point: It's not a flammability reagent

SAFETY DATA SHEETS

.....
 microdot® PRO Control Solutions

10. Stability and reactivity Conditions to avoid: moisture and light Hazardous decomposition products: None
11. Toxicological information Acute toxicity: Not testing Chronic effects of overexposure: None currently known Inhalation, skin contact and eye contact: Not considered health risks
12. Ecological information Ecological effects: None determined
13. Disposal considerations Product: microdot PRO Glucose Control Solution, before or after used, must be disposed of in compliance with the respective regulations. Packaging: product packaging must be disposed of in compliance with the country-specific regulations or must be passed to a packaging return system.
14. Transport information This product is not classified as dangerous for transport. Not restricted according to IATA & DGR regulation.
15. Regulatory information Not hazardous
16. Other information None

Chapter 8

SAFETY DATA SHEETS

microdot® Bleach Wipe

Revised 5/28/2021

Section 1: Identification

PRODUCT NAME: microdot® BLEACH WIPE
EPA REGISTRATION NUMBER: 37549-1-88459
PRODUCT DESCRIPTION: Hospital cleaner disinfection wipe pre-saturated with bleach. Mild bleach odor.
TRADE NAME: microdot® BLEACH WIPE
GENERAL USE: Hospital disinfectant wipe
CHEMICAL FAMILY: Sodium hypochlorite

MANUFACTURER: MEDLINE INDUSTRIES, INC.
ADDRESS: 3 LAKES DRIVE, NORTHFIELD, IL 60093

DISTRIBUTED BY: CAMBRIDGE SENSORS USA, LLC
ADDRESS: 23866 W. INDUSTRIAL DR. N., PLAINFIELD, IL 60585

TELEPHONE NUMBER FOR INFORMATION / CUSTOMER SERVICE: 800-633-5463
24-HOUR EMERGENCY TELEPHONE NUMBER: CHEMTREC 800-424-9300

Section 2: Hazards Identification

EMERGENCY OVERVIEW:

Avoid contact with eyes, skin, and clothing as this product may produce irritation. Do not allow this product to contact acidic materials as hazardous chlorine gas may be released.

POTENTIAL HEALTH EFFECTS

INHALATION: No adverse effects are anticipated from inhalation.
SKIN: Normal exposure (contact) is not likely to cause significant skin irritation.
EYES: Causes moderate eye irritation.
INGESTION: May cause gastrointestinal irritation and upset.
CARCINOGENICITY: NTP? NO IARC MONOGRAPHS? NO OSHA REGULATED? NO
CALIFORNIA, Prop.65? NO

Section 3: Composition/Information on Ingredients

Hazardous Components	% (by Weight)	CAS#
Sodium hypochlorite	<1.05%	7681-52-9

Notes: * The balance of ingredients not listed above are non-hazardous as defined in the OSHA hazard communication standard 29CFR 1910.1200.

SAFETY DATA SHEETS

.....

microdot® Bleach Wipe

Section 4: First Aid Measures

INHALATION:	No specific treatment - suspected hazard by this route is minimal. Note to Physician: No specific antidote. Supportive care. Treatment based on judgment of the physician in response to reactions of the patient.
EYES:	If in eyes, hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eyes. Seek medical attention if irritation persists.
SKIN:	Wash with soap and water. No further first aid should be required.
INGESTION:	No specific treatment - suspected hazard by this route is minimal.

Section 5: Fire Fighting Measures

GENERAL HAZARDS:	Product is minimally flammable $FP \geq 101^{\circ}\text{C}$ (215°F). Chlorine may be released from this product in the presence of acids.
EXTINGUISHING MEDIA:	Water fog, carbon dioxide and dry chemical to fight surrounding fire.
FIRE FIGHTING PROCEDURES:	Wear SCBA when fighting fires involving this as a precaution.
UNUSUAL FIRE AND EXPLOSION:	None.
HAZARDOUS COMBUSTION PRODUCTS:	Carbon Monoxide, Carbon Dioxide, smoke, organic vapors from dried and heated towels in fore conditions.

Section 6: Accidental Release Measures

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED:

Isolate damaged goods. Spills should be diluted with water, then absorbed with sand, clay, or earth. Dispose of saturated absorbent materials appropriately since spontaneous heating may occur.

Section 7: Handling and Storage

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE:

Isolate damaged goods. Spills should be diluted with water, then absorbed with sand, clay, or earth. Dispose of saturated absorbent materials appropriately since spontaneous heating may occur.

VENTILATION:	Good general ventilation should be sufficient for most conditions.
RESPIRATORY PROTECTION:	No respiratory protection should be needed.
PROTECTIVE CLOTHING:	No precautions other than clean body covering clothing should be needed. Gloves are recommended.
EYE PROTECTION:	Use safety glasses or equivalent protection to avoid eye contact.

Section 8: Exposure Controls / Personal Protection

HAZARDOUS COMPONENTS	NIOSH				ACGIH			OSHA	
	TWA ppm	TWA mg/m ³	STEL ppm	STEL mg/m ³	TLV/TWA ppm	TWA mg/m ³	PEL ppm	PEL mg/m ³	
Sodium Hypochlorite				10 IDLH		2		2	

PERSONAL PROTECTION

RESPIRATORY PROTECTION:	A respiratory protection program that meets OSHA's 29 CFR 1910.134, ANSI Z88.2 requirements must be followed whenever workplace concentrations of this product in air exceed the published TLV's. Impervious rubber, or nitrile gloves are advised if prolonged or repeated exposure is likely.
PROTECTIVE GLOVES:	Use safety glasses with protective side shields to avoid eye contact.
EYE PROTECTION:	
OTHER PROTECTIVE CLOTHING OR EQUIPMENT:	Not required.
WORK / HYGIENIC PRACTICES:	Wash with soap and water after contact.

Chapter 8

SAFETY DATA SHEETS

microdot® Bleach Wipe

Section 9: Physical and Chemical Properties

APPEARANCE AND ODOR

Clear, colorless solution with a mild bleach odor.

pH

10.0-12.0

BOILING POINT / BOILING RANGE

100°C (212°F)

FLASH POINT

> 1 01 QC (>215QF)

FLAMMABLE LIMITS

LEL: NE UEL: NE

AUTOIGNITION TEMPERATURE

NE

VAPOR PRESSURE

17.5mmHg at 20 °C

SPECIFIC GRAVITY (WATER = 1)

1.015@25QC.

SOLUBILITY IN WATER

Completely soluble (for liquid) .

VISCOSITY

NA

VAPOR DENSITY (AIR = 1)

NR

EVAPORATION RATE (WATER = 1)

NR

Section 10: Stability and Reactivity

STABILITY

The product is stable under normal use and storage conditions.

CONDITIONS TO AVOID:

Excessive heat and light exposure. Avoid contact with incompatible materials listed in the following section:

INCOMPATIBILITY (MATERIALS TO AVOID):

Avoid contact with acids, reducing agents, ammonia, or heavy metals such as nickel, cobalt, copper, and iron.

Reacts with other household chemicals such as toilet bowl cleaners, rust removers, vinegar, acids or ammonia containing products to produce hazardous gases, such as chlorine and other chlorinated species.

HAZARDOUS DECOMPOSITION OR BYPRODUCTS:

Chlorine in the presence of acids.

HAZARDOUS POLYMERIZATION:

Will not occur.

CONDITIONS TO AVOID:

None related to polymerization.

Section 11: Toxicological Information

HAZARDOUS COMPONENTS

CAS

**LD50 of Ingredient
(Specify Species and Route)**
Oral, mouse: LD50 = 5800 mg/kg

**LC50 of Ingredient
(Specify Species)**
NE

Sodium hypochlorite

7681-52-9

In the case of medical emergency, contact your local poison control center.

Section 12: Ecological Information

No information is available for this blended product.

SAFETY DATA SHEETS

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microdot® Bleach Wipe

Section 13: Disposal Considerations

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE DISPOSAL: Wastes resulting from the use of microdot® BLEACH WIPE must be disposed of on site or at an approved waste disposal facility. Do not flush wipe down the toilet.

CONTAINER HANDLING: Nonrefillable rigid canister. Do not re-use or refill this canister. Recycle empty canister or discard in trash.

Section 14: Transport Information

PROPER SHIPPING NAME: Not regulated

IATA HAZARD CLASS / Pack Group: Contact Manufacturer

DOT HAZARD CLASS I Pack Group: Not regulated

IMDG HAZARD CLASS: Contact Manufacturer

REFERENCE: 49CFR172, 49CFR173

RID/ADR Dangerous Goods Code: Contact Manufacturer

UN / NA IDENTIFICATION NUMBER: Not Regulated

UN TDG Class I Pack Group: Contact Manufacturer

LABEL: Not Regulated

Hazard Identification Number (HIN): Contact Manufacturer

HAZARD SYMBOLS: NONE

Refer to 49CFR172 and 49CFR173 for pertinent regulations

Note: Transportation information provided is for reference only. Client is urged to consult CFR 49 parts 100 - 177, IMDG, IATA, EU, United Nations TOG, and WHMIS (Canada) TOG information manuals for detailed regulations and exceptions covering specific container sizes, packaging materials and methods of shipping.

Section 15: Regulatory Information

TSCA (USA - Toxic Substance CONTROL ACT): Listed.

SARA TITLE III (USA - Superfund Amendments and Reauthorization Act):

Acute Health: Yes

Chronic Health:

No

Fire: No

Sudden Release of Pressure: No

Reactive: No

313 REPORTABLE INGREDIENTS: None reportable.

ERCLA (USA - Comprehensive Response Compensation and Liability Act) : CAS# 7681-52-9: 100 lb final RQ; 45.4 kg final RQ. CAS# 1310-73-2: 1000 lb final RQ; 454 kg final RQ.

Section 16: Other Information

Legend: NA=Not Applicable

NE=Not established

NR=Not Reported

HMIS HAZARD RATINGS

HEALTH:

2

0 = INSIGNIFICANT

FLAMMABILITY:

0

1 = SLIGHT

PHYSICAL HAZARD:

1

2 = MODERATE

PERSONAL PROTECTIVE:

B

3 = HIGH

EQUIPMENT:

Glasses and gloves

4 = EXTREME

NFPA HAZARD RATINGS

HEALTH:

0

0 = NONE

FLAMMABILITY:

0

1 = SLIGHT / LITTLE

REACTIVITY:

1

2 = MODERATE

SPECIAL HAZARDS::

OX

3 = HIGH / SERIOUS

4 = EXTREME

Chapter 8

SAFETY DATA SHEETS

microdot® Minute Wipe

Product and Company Identification

Product identifier	NAIC 88494-1 (Wipe)
Other means of identification	microdot® Minute Wipe
Recommended use	Disinfectant
Recommended restrictions	None known.
Manufacturer/Importer/Supplier/Distributor information	
Manufacturer	
Company name	Cambridge Sensors USA, LLC
Address	23866 W. Industrial Drive N. Plainfield, IL 60585 United States
Telephone	1.877.374.4062
E-mail	info@microdotcs.com
Emergency phone number	1.877.374.4062

Section II - Hazards Identification

Physical hazards	Flammable liquids	Category 2
Health hazards	Acute toxicity, inhalation	Category 4
	Serious eye damage/eye irritation	Category 2A
	Specific target organ toxicity, single exposure	Category 3 respiratory tract irritation
	Specific target organ toxicity, single exposure	Category 3 narcotic effects
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		
Signal word	Danger	
Hazard statement	Highly flammable liquid and vapor. Causes serious eye irritation. Harmful if inhaled. May cause respiratory irritation. May cause drowsiness or dizziness.	
Precautionary statement		
Prevention	Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Keep container tightly closed. Ground/bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Avoid breathing mist or vapor. Wash thoroughly after handling. Use only outdoors or in a well-ventilated area. Wear protective gloves/eye protection/face protection.	
Response	In case of fire: Use appropriate media to extinguish. If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor// if you feel unwell.	
Storage	Store in a well-ventilated place. Keep container tightly closed. Keep cool. Store locked up.	
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.	
Hazard(s) not otherwise classified (HNOC)	None known.	
Supplemental information	Although the product as a whole is in solid format, the product does not meet the OSHA HCS definition of a flammable solid as per Appendix B to 1910.1200 - Physical Hazard Criteria, section B.7.1 and B. 7.2. This is a registered EPA product. The product labeling is in compliance with EPA regulations and guidelines.	

SAFETY DATA SHEETS

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microdot® Minute Wipe

Section III - Composition/Information on Ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Ethanol		64-17-5	60-80
Composition comments	US GHS: The exact percentage (concentration) of composition has been withheld as a trade secret in accordance with paragraph (i) of §1910.1200.		

Section IV - First Aid Measures

Inhalation	If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell.
Skin contact	If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
Eye contact	If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
Ingestion	Rinse mouth. Do not induce vomiting. Get medical attention if symptoms occur. Never give anything by mouth if victim is unconscious, or is convulsing. Obtain medical attention.
Most important symptoms/effects, acute and delayed	Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Vapors have a narcotic effect and may cause headache, fatigue, dizziness and nausea.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. In case of shortness of breath, give oxygen. Symptoms may be delayed.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Take off all contaminated clothing immediately. If you feel unwell, seek medical advice (show the label where possible). Show this safety data sheet to the doctor in attendance. Wash contaminated clothing before reuse. Keep away from sources of ignition. No smoking. Avoid contact with eyes and skin. Wear rubber gloves and safety glasses with side shields. Keep out of reach of children.

Section V- Fire Fighting Measures

Suitable extinguishing media	Dry chemical, CO2, water spray or regular foam.
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Firefighters should wear full protective clothing including self contained breathing apparatus.
Fire-fighting equipment/instructions	In case of fire and/or explosion do not breathe fumes. Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	Solid containing flammable liquid

Section VI- Accidental Release Measures

Personal precautions, protective equipment and emergency procedures	Remove all possible sources of ignition in the surrounding area. Wear appropriate protective equipment and clothing during clean-up. Do not breathe vapor. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Take precautionary measures against static discharge. Use only non-sparking tools. Pick up and discard towlette.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground. Use appropriate containment to avoid environmental contamination.

Chapter 8

SAFETY DATA SHEETS

microdot® Minute Wipe

Section VII - Handling and Storage

Precautions for safe handling	Vapors may form explosive mixtures with air. Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Do not smoke. Minimize fire risks from flammable and combustible materials (including combustible dust and static accumulating liquids) or dangerous reactions with incompatible materials. Avoid breathing vapor. Avoid contact with eyes, skin and clothing. Avoid prolonged exposure. Use only outdoors or in a well-ventilated area. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Wash thoroughly after handling. Keep container tightly closed. When using do not eat or drink.
Conditions for safe storage, including any incompatibilities	Store locked up. Keep away from heat, sparks and open flame. Avoid spark promoters. Eliminate sources of ignition. Store in a closed container away from incompatible materials. Store in a cool, dry place out of direct sunlight. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS). Keep out of reach of children.

Section VIII - Exposure Controls/Personal Protection

Occupational exposure limits

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value
Ethanol (CAS 64-17-5)	PEL	1900 mg/m3 1000 ppm

US. ACGIH Threshold Limit Values

Components	Type	Value
Ethanol (CAS 64-17-5)	STEL	1000 ppm

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Ethanol (CAS 64-17-5)	TWA	1900 mg/m3 1000 ppm

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields.

Skin protection

Hand protection

Rubber gloves. Confirm with a reputable supplier first.

Other

Wear suitable protective clothing. Wear appropriate chemical resistant clothing. As required by employer code.

Respiratory protection

Where exposure guideline levels may be exceeded, use an approved NIOSH respirator.

Thermal hazards

Not applicable.

General hygiene considerations

When using do not smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

SAFETY DATA SHEETS

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microdot® Minute Wipe

Section IX - Physical and Chemical Properties

Appearance	Clear Liquid saturated on wipe
Physical state	Liquid.
Form	Liquid saturated on wipe
Color	Colorless
Odor	Alcohol
Odor threshold	Not available.
pH	3.7 @ 77°F (liquid)
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Pour point	Not available.
Specific gravity	Not available.
Partition coefficient (n-octanol/water)	Not available.
Flash point	65.3 °F (18.5 °C) Tag Closed Cup (liquid)
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	3.23 cSt @ 68°F (liquid)
Other information	
Density	0.86 (liquid)

Section X - Stability and Reactivity

Reactivity	This product may react with strong oxidizing agents.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Chemical stability	Stable under recommended storage conditions.
Conditions to avoid	Avoid heat, sparks, open flames and other ignition sources. Avoid temperatures exceeding the flash point. Do not mix with other chemicals.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	May include and are not limited to: Oxides of carbon.

SAFETY DATA SHEETS

microdot® Minute Wipe

Section XI - Toxicological Information

Information on likely routes of exposure

Ingestion	Expected to be a low ingestion hazard.
Inhalation	Vapors have a narcotic effect and may cause headache, fatigue, dizziness and nausea. Harmful if inhaled. Prolonged inhalation may be harmful.
Skin contact	No adverse effects due to skin contact are expected. Non-irritating based on test data.
Eye contact	Causes serious eye irritation.

Symptoms related to the physical, chemical and toxicological characteristics
Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting.

Information on toxicological effects

Acute toxicity Harmful if inhaled. Narcotic effects. May cause respiratory irritation.

Product	Species	Test Results
NAIC 88494-1 (Wipe) (CAS Mixture)		
Acute		
<i>Dermal</i>		
LD50	Rat	> 5000 mg/kg, Tested
<i>Inhalation</i>		
LC50	Rat	> 2.1 mg/l, Tested
<i>Oral</i>		
LD50	Rat	> 5000 mg/kg, Tested
Components	Species	Test Results
Ethanol (CAS 64-17-5)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	> 15800 mg/kg
<i>Inhalation</i>		
LC50	Mouse	39 mg/l, 4 Hours
	Rat	31623 ppm, 4 Hours
		20000 ppm, 10 Hours
<i>Oral</i>		
LD50	Dog	5500 mg/kg
	Guinea pig	5600 mg/kg
	Mouse	3450 mg/kg
	Rat	7060 mg/kg

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Exposure minutes Not available.

Erythema value Not available.

Oedema value Not available.

Serious eye damage/eye irritation Causes serious eye irritation.

Corneal opacity value Not available.

Iris lesion value Not available.

Conjunctival reddening value Not available.

Conjunctival oedema value Not available.

Recover days Not available.

Respiratory or skin sensitization

Respiratory sensitization Not available.

Skin sensitization This product is not expected to cause skin sensitization.

Germ cell mutagenicity Non-hazardous by OSHA criteria.

Carcinogenicity Non-hazardous by OSHA criteria.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity Non-hazardous by OSHA criteria.

Specific target organ toxicity - single exposure Respiratory tract irritation. Narcotic effects.

Specific target organ toxicity - repeated exposure Not classified.

Aspiration hazard Not available.

Chronic effects Prolonged inhalation may be harmful.

Further information Not available.

SAFETY DATA SHEETS

microdot® Minute Wipe

Section XII - Ecological Information

Ecotoxicity	See below		
Components		Species	Test Results
Ethanol (CAS 64-17-5)			
Crustacea	EC50	Daphnia	11744.5 mg/L, 48 Hours
Aquatic			
Crustacea	EC50	Water flea (Daphnia magna)	7.7 - 11.2 mg/l, 48 hours
Fish	LC50	Fathead minnow (Pimephales promelas)	> 100 mg/l, 96 hours
Persistence and degradability	No data is available on the degradability of this product.		
Bioaccumulative potential	No data available.		
Partition coefficient n-octanol / water (log Kow)			
Ethanol		-0.31	
Mobility in soil	No data available.		
Mobility in general	Not available.		
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.		

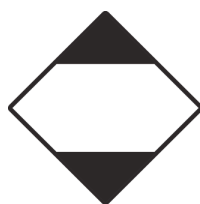
Section XIII - Disposal Considerations

Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. This material and its container must be disposed of as hazardous waste. Incinerate the material under controlled conditions in an approved incinerator. Do not incinerate sealed containers. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. If discarded, this product is considered a RCRA ignitable waste, D001. Dispose of contents/container in accordance with local/regional/national/international regulations.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	D001: Waste Flammable material with a flash point <140 F The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

Section XIV - Transport Information

U.S. Department of Transportation (DOT)	
Basic shipping requirements:	
UN number	UN1992
Proper shipping name	Flammable liquids, toxic, n.o.s. (Ethanol)
Hazard class	Limited Quantity - US
Packing group	II
Special provisions	IB2, T7, TP2, TP13
Packaging exceptions	<0.3 Gal-Consumer Commodity ORM-D/Limited Quantity
Packaging non bulk	202
Packaging bulk	243

DOT



Chapter 8

SAFETY DATA SHEETS

microdot® Minute Wipe

Section XII - Regulatory Information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - No
Fire Hazard - Yes
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance No

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

Food and Drug Administration (FDA) Not regulated.

US state regulations Ethanol is not considered to be a Prop 65 component for this product. The product is not an alcoholic beverage for consumption.

US - California Hazardous Substances (Director's): Listed substance

Ethanol (CAS 64-17-5) Listed.

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

Ethanol (CAS 64-17-5) Listed.

US - Illinois Chemical Safety Act: Listed substance

Ethanol (CAS 64-17-5) Listed.

US - Louisiana Spill Reporting: Listed substance

Ethanol (CAS 64-17-5) Listed.

US - Minnesota Haz Subs: Listed substance

Ethanol (CAS 64-17-5) Listed.

US - New Jersey RTK - Substances: Listed substance

Ethanol (CAS 64-17-5) Listed.

US - Texas Effects Screening Levels: Listed substance

Ethanol (CAS 64-17-5) Listed.

US. Massachusetts RTK - Substance List

Ethanol (CAS 64-17-5) Listed.

US. Pennsylvania RTK - Hazardous Substances

Ethanol (CAS 64-17-5) Listed.

US. Rhode Island RTK

Not regulated.

Country(s) or region	Inventory name	On inventory (yes/no)*
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s)

SAFETY DATA SHEETS

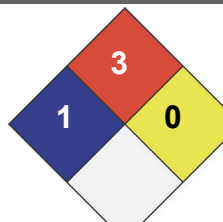
microdot® Minute Wipe

Section XII - Other Information

LEGEND	
Severe	4
Serious	3
Moderate	2
Slight	1
Minimal	0

Disclaimer

HEALTH	* 1
FLAMMABILITY	3
PHYSICAL HAZARD	0
PERSONAL PROTECTION	X



The information in the sheet was written based on the best knowledge and experience currently available. Information contained herein was obtained from sources considered technically accurate and reliable. While every effort has been made to ensure full disclosure of product hazards, in some cases data is not available and is so stated. Since conditions of actual product use are beyond control of the supplier, it is assumed that users of this material have been fully trained according to the requirements of all applicable legislation and regulatory instruments. No warranty, expressed or implied, is made and supplier will not be liable for any losses, injuries or consequential damages which may result from the use of or reliance on any information contained in this document.

Issue date

30-June-2015

Further information

For an updated SDS, please contact the supplier/manufacturer listed on the first page of the document.

Other information

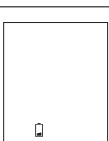
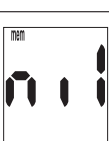
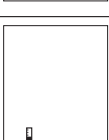
This Safety Data Sheet was prepared to comply with the current OSHA Hazard Communication Standard (HCS) adoption of the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).

Prepared by

Cambridge Sensors USA, LLC Phone: 1.877.374.4062

TROUBLESHOOTING THE *microdot*[®] PRO METER

This section details the significant display screen messages and error codes you may encounter when using the microdot[®] PRO Meter and microdot[®] PRO Blood Glucose Test Strip.

Message	What it Means	What You Should Do
	Damaged meter electronic or test strip	- Remove the batteries and turn the meter on again. - Remove the test strip and insert a new test strip. - If problem persists, call us at 1.877.374.4062 Monday through Friday from 9am to 5pm CST
	Used or contaminated test strip	Repeat the test with a new test strip. Wait until you see the flashing blood drop icon before you add blood or control solution sample.
	Not enough sample on the test strip to start	Remove the test strip and repeat the test with a new test strip. See Testing Blood Glucose on page 19.
	Premature sample application	Remove the test strip and repeat the test with a new test strip, apply blood AFTER flashing blood drop icon appears. See Testing Blood Glucose on page 19.
	Test result higher than 600 mg/dL	Retest patient using a new test strip, discard first drop of blood before taking a sample.
	Test result lower than 20 mg/dL	Retest patient using a new test strip, discard first drop of blood before taking a sample.
	Low battery	Change the batteries according to instructions for Inserting (or Changing) the Battery on page 6.
	No memorized results in the meter	- Check if the date and time on the meter is set up. See Setting Up the New System on page 6. - Start testing the blood glucose, see Testing Blood Glucose on page 22.
	Temperature out of range	Move the meter into an area that is between 41°F~113°F, and allow 10 to 15 minutes for it to reach the new temperature.

microdot[®] PRO METER QUICK START VIDEOS

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Please scan the corresponding QR code with your phone's camera to watch a short video.



Setting Up
and Navigating the
Glucometer



Control Solution
Testing
Procedure



Performing a
Blood Glucose
Test



Troubleshooting
Errors

MANUFACTURER CLEANING INSTRUCTIONS

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Cleaning & Disinfecting the microdot® PRO Meter

Prior to cleaning & disinfecting, remove the orange, protective microdot® Meter Sleeve. Cambridge Sensors USA, LLC recommends cleaning & disinfecting the microdot® PRO Meter using an EPA Registered 1:10 dilution of .525% - .615% sodium hypochlorite, or an EPA-registered tuberculocidal disinfectant wipe.

The recommendation is in accordance with C.D.C. Guidelines for Disinfection and Sterilization.

Cambridge Sensors USA, LLC offers two ready to use products to meet cleaning & disinfection requirements. The ready to use microdot® Bleach Wipe and microdot® Minute Wipe. The microdot® Bleach Wipe is premoistened with a 1:10 dilution. The microdot® Minute Wipe is an EPA-registered tuberculocidal.

For easy cleaning & disinfecting Cambridge Sensors USA, LLC offers the microdot® Disinfection System which includes the user friendly microdot® Meter Case & Timer to insure proper dwell time.

Note: Over exposure (contact time) may damage meter. When cleaning & disinfecting the microdot® PRO Meter take extreme care not to get liquid in the test strip dock or key code parts.

Cambridge Sensors USA, LLC

Customer Service available from 8am - 5pm CST Monday - Friday

Toll free 1.877.374.4062 | www.microdotcs.com

microdot[®] PRO METER LIMITATIONS

- Inaccurate results may occur in severely hypotensive individuals or patients in shock.
- Inaccurate low results may occur for individuals experiencing a hyperglycemic hyperosmolar state, with or without ketosis.
- This meter has not been evaluated in the critically ill.
- Not for use on neonates.
- Altitude higher than 10,335 feet may cause inaccurate results.
- Hematocrit range higher than 70% or lower than 10% can cause inaccurate results.
- Severe dehydration may lead to inaccurate blood glucose test result.
- For In vitro diagnostic only.
- For over the counter use.
- Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly).
- For multiple-patient use.
- Alternative site measurements should never be used to calibrate continuous glucose monitors (CGMs).
- Alternative site measurements should never be used for insulin dosing calculations.

DO NOT use plasma or serum samples.

DO NOT test on arterial blood samples.

Xylose levels above 7.5 mg/dL may give falsely elevated results.

Acetaminophen levels above 7.5 mg/dL may cause inaccurate results (therapeutic concentration: 2mg/dL).

Tolazamide levels above 23 mg/dL may cause falsely high test results (therapeutic concentration: 23mg/dL).

Paralidoxime levels (PAM) above 125 mg/dL may cause falsely high test results (therapeutic concentration: 40mg/dL).

Uric acid levels above 10.25 mg/dL may cause falsely low test results (reference range: 2.5-8 mg/dL).

Chapter 13

NOTES

[illegible]