

**Polytel[®] GMA
Glucose Meter Accessory
Model PWR-08-03**

USER MANUAL

Version: 2

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Table of Contents

1 INTRODUCTION.....4

1.1 OVERVIEW4

1.2 WHO IS THIS FOR?.....5

2 PARTS OF THE GMA6

2.1 RED LIGHT6

2.2 BATTERY COMPARTMENT8

2.3 SIZE OF YOUR GMA8

3 OPERATING INSTRUCTIONS.....8

3.1 CHANGING THE BATTERIES.....8

3.2 CONNECTING THE DEVICES11

3.3 PLACEMENT OF THE GMA AND RECEIVING STATION.14

3.4 HOW TO USE YOUR GMA.....14

3.5 IF THE TRANSMISSION DIDN'T SEND17

3.6 DISCONNECTED GLUCOSE METER.....18

3.7 WHEN YOU'RE TRAVELING.....19

 3.7.1 *Traveling in France, Spain, or Japan*19

3.8 TROUBLESHOOTING.....20

4 SAFETY INFORMATION.....21

4.1 PATIENT SAFETY21

4.2 ELECTRICAL SAFETY22

4.3 COMPLIANCE INFORMATION22

 4.3.1 *Compliance Requirements*.....23

 4.3.2 *Compliance Statement*.....23

4.4 ABOUT THE LABEL AT THE BOTTOM OF THE GMA.....24

5 OPERATOR MAINTENANCE25

5.1 PERIODIC MAINTENANCE25

5.2 CLEANING YOUR GMA.....26

6 TECHNICAL SPECIFICATIONS26

6.1 BATTERIES.....26
 6.2 TEMPERATURES27
 6.3 COMPATIBILITY WITH OTHER ELECTRICAL MEDICAL
 EQUIPMENT27
 6.4 SYSTEM AVAILABILITY.....28
7 TRADEMARKS.....28
8 INDEX29

1 Introduction

1.1 Overview

Welcome to the world of wireless medical monitoring. In this pamphlet, you will learn how to use and maintain your Polytel® GMA Glucose Meter Accessory.

The GMA is an easy-to-use accessory that lets you send the glucose readings you take with your LifeScan OneTouch® Ultra® glucose meter wirelessly to a receiving station.

This no more worrying about writing down the test results and carrying them in to your doctor every visit—it is all done automatically in your own home.

There are three parts to sending your readings wirelessly:

- You measure your glucose on the LifeScan OneTouch Ultra glucose meter.
- The GMA receives the reading from the OneTouch Ultra and sends it wirelessly to the receiving station.
- The receiving station receives, stores, and sends your readings to your service provider – usually your doctor’s office or a monitoring service. The station is a separate device that is either a self-contained box,

called an “access point,” or your personal computer, cell phone, or handheld computer provided by your monitoring service. Your monitoring service can explain how to use the receiving station.

To use the GMA, all you have to do is take the reading using OneTouch Ultra as usual. Everything else is done automatically for you.

To make sure all data is sent to your provider, if the GMA is unable to find a receiving station, it will save the reading along with the date and time you took it. The old reading will be sent along with the next reading.

1.2 Who is this for?

The GMA is intended for diabetic patients who want to monitor their glucose levels remotely. It can be used by patients in their homes and in their daily lives.

2 Parts of the GMA

Your GMA is easy to maintain, set up and use.

The most important part to pay attention to is the red light at the bottom right edge of the device. Different blinking patterns tell you when the GMA is sending data, whether it was sent successfully or not, and when it is time to change the batteries.

2.1 Red light

The GMA has a small red indicator light that blinks in different patterns when it is doing different things.



Figure 1: Red light indicates status of the GMA

Here are the possible light patterns and their meanings:

Light Looks Like...	Speed / Length	It means...
On (no blinking)	Up to 20 seconds	GMA is receiving reading from OneTouch Ultra.
Blinking	1 blink per second	GMA connecting to receiving station. Please be patient.
Very fast blinking	2 blinks per second for 1-2 seconds	GMA sending data to receiving station.
Very fast blinking	2 blinks per second for 10+ seconds	Replace batteries. (See p. 8.)
Slow blinking	1 blink per 10 seconds	Last attempt to send data unsuccessful, waiting to retry.
Off	n/a	Either: <ul style="list-style-type: none"> • Successfully sent data. or: <ul style="list-style-type: none"> • Data not successfully sent, will send with next reading. (See p. 17.)

2.2 Battery Compartment

You can open the battery compartment by sliding the lid in the direction of the arrow then allowing it to swing open:

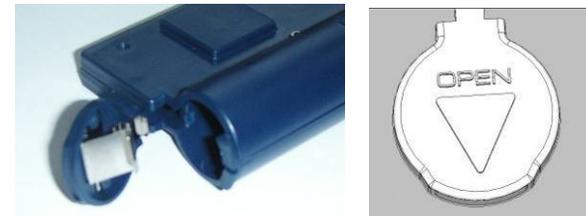


Figure 2: Battery lid. Slide lid in direction of arrow and allow it to swing open

2.3 Size of your GMA

2.85 inches x 0.8 inches x 1.8 inches (72mm x 20mm x 45mm)

3 Operating Instructions

3.1 Changing the batteries

The GMA uses two Lithium CR2-size cell batteries that should last several months. You can buy new Lithium CR2-size batteries at most drugstores or grocery stores.

Tip: Your batteries will last longer if you remove them if you will not be using the GMA for a month or longer.

It is time to change the batteries when the red light on the GMA blinks fast for at least 10 seconds after a new reading. Here is how you change the batteries

1. Open the battery compartment by sliding the lid in the direction indicated by the arrow labeled **OPEN** on the lid and let the lid open.



Figure 3: Slide open the lid to change the batteries

2. Insert the first Lithium CR2-size battery with the negative end (–) down and the positive end (+) up.



3. Repeat step 2 for the second battery.

Note: Always replace both batteries at the same time and make sure the batteries are from the same manufacturer.



Putting the batteries in backwards could make the device get hot or make the batteries leak. Please pay attention to the instructions.

4. Close the battery compartment by bringing the lid gently down toward the batteries and sliding it in the direction opposite the **OPEN** arrow until the lid stops.
5. If the red light still flashes for 10 seconds or longer, repeat steps 1 through 4 and:
 - Check that you inserted the batteries in the right direction.
 - Try replacing with a different pair of Lithium CR2-size batteries.
 If you are still having trouble, see the “Troubleshooting” section on page 20.

3.2 Connecting the devices

Before you can start using the GMA, you need to connect it to the OneTouch Ultra glucose meter.

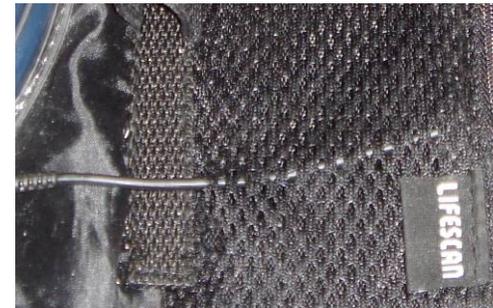
- 1) Slide the OneTouch Ultra into the clear plastic pocket in its carrying case.



- 2) Put the cable from the GMA in the zippered mesh pocket of the carrying case.



- 3) Thread the cable through the mesh pocket, in through the zippered opening and out through a hole in the mesh near the meter.



Tip: If you are having trouble threading the cable through the mesh pocket, try cutting a small slit (no more than ¼ inch) in the mesh.

- 4) Plug the cable from the GMA into the bottom of the OneTouch Ultra and press firmly into place.



Plug in jack and press firmly into place



NOTE: Connect the GMA ONLY to a LifeScan OneTouch Ultra. Connecting it to any other device may make your readings inaccurate or damage one or both devices.

- 5) Put the GMA in the mesh pocket:



- 6) Close and zip the case. The next step is setting up the receiving station if this has not already been done.

3.3 Placement of the GMA and receiving station

Various types of barriers, such as walls, can reduce the range of wireless devices. Your GMA will work best if it is in the same room as the receiving station. (Remember: your receiving station is the separate box, personal computer, cell phone, or handheld device.)



Warning: Do **not** put the GMA on a metal surface or in a metal box or enclosure. This may interfere with its ability to send data.

When the devices are working together correctly, the red light on the GMA comes on and starts blinking right after you take a new reading, then goes out when the reading is sent. See page 7 to learn more about the red light.

3.4 How to use your GMA

1. Insert the glucose test strip into the OneTouch Ultra glucose meter and take your reading as you normally would. Instructions on using your OneTouch Ultra should have come with the glucose meter.
2. Remove the test strip as usual.
3. After you remove the test strip:
 - a. The red light on the GMA turns on automatically.

- b. The OneTouch Ultra displays **PC** on the screen. This shows that it is sending the reading to the GMA. The **PC** indication will stay on for two minutes. This is normal.



Figure 4: PC shows on the OneTouch Ultra when the GMA is receiving your readings.

- c. The GMA red light begins blinking off and on. This means that it is sending your reading to the receiving station.



After taking your glucose reading, it may take a minute or two to send the reading to the receiving station. **Please be patient**—do not press any buttons or disconnect the GMA until the light has completely stopped blinking or your results may not be sent.



Figure 5: Blinking light usually means your information is being sent. Please be patient.



IMPORTANT: If OneTouch Ultra screen does **not** show **PC** or the red light does **not** come on shortly after taking a new reading:

- Check that the GMA cable is firmly plugged into the OneTouch Ultra.
- Try replacing both batteries (see page 8).

- See page 20 if you are still having problems.

When the GMA sends your information, the power level of the batteries is sent along with your reading. Your monitoring service may tell you it is time to replace the batteries, even before you notice any problems.

That's it—you don't have to do anything more. After the reading reaches the receiving station, the GMA light turns off. A couple of minutes later, the **PC** disappears from the OneTouch Ultra device.

3.5 If the Transmission Didn't Send

If your transmission was not sent successfully, the GMA will try again 1 minute later and then again 2 minutes later.

If all three tries fail, the GMA saves the reading along with the time and date it was taken and turns itself off. The next time you take a new reading, it sends both the new and the stored readings.

Tip: If you want to send the stored reading(s) without taking a new one:

1. Insert a test strip as if you are taking a new reading.
2. Remove the strip without taking a blood sample.

You will see the **PC** come on, as during a normal transmission

3.6 Disconnected glucose meter

Any readings taken when the GMA is not connected to the OneTouch Ultra are stored along with the date and time taken. The next time you take a new reading after the devices are connected again, both the stored and new readings are sent to the receiving station.

3.7 When You're Traveling

If you are not at home or near your regular receiving station, the GMA can send the readings to a different station.

Please speak with your monitoring service to set this up.

3.7.1 Traveling in France, Spain, or Japan

The device uses several radio channels. Some of these are not allowed in France, Spain, or Japan. If you live in or plan to travel to these countries, please contact Polymap Wireless.

3.8 Troubleshooting

What's Wrong?	What Caused It?	What To Do
Red light doesn't come on	Weak/missing batteries	Replace batteries (see p. 8).
	Disconnected cable	Plug cable firmly into OneTouch Ultra (see p. 12).
Can't send even after several tries (light is on)	Receiving station may not be working properly	Move receiving station closer to GMA or see manual for receiving station.
PC does not show on meter	Weak/missing batteries	Replace batteries (see p. 8).
	Disconnected cable	Plug cable firmly into OneTouch Ultra (see p. 11).
	Damaged or frayed cable	Send GMA to Polymap Wireless for repair.

4 Safety Information

We are committed to your safety. Please read these warnings and cautions.

4.1 Patient Safety



CAUTION! Do **not** share your One Touch Ultra or GMA with **anyone** else. Letting someone else use your GMA will cause his or her readings to be mistaken for yours.



NOTE: Polymap Wireless is not responsible for the reading, diagnosis, or electrical safety of the OneTouch Ultra glucose meter itself. The Polytel GMA is a data transmission system only.



WARNING: Changes made to the product, unless expressly approved by *Polymap Wireless, LLC* could void the user's license for and the warranty of the device.



CAUTION! Only use Lithium CR2-size batteries. Using any other type of battery may cause an explosion.

4.2 Electrical Safety

Only authorized maintenance staff should disassemble the GMA. (This does not include changing the batteries.)

The GMA is classified as CLASS II equipment as per IEC60601-1 and Class II Medical Devices per 21CFR.

The One Touch Ultra meter is approved for use by its manufacturer. Polymap Wireless is not responsible for its diagnostic accuracy or its electrical safety.



WARNING! Never operate this device in an area where there is a risk of explosion. Using electrical equipment in the presence of flammable anesthetics or oxygen may cause an explosion.

Polymap Wireless personnel must do all servicing of your GMA.

4.3 Compliance Information

This section is about the telemetry system regulatory compliance requirements and the manufacturer's responsibilities.

4.3.1 Compliance Requirements

Polymap Wireless is responsible for the effects of safety, reliability, and performance of the GMA as long as:

- You use the equipment according to the instructions in this manual.
- All repairs, changes, assembly operations, and extensions are done only by Polymap Wireless.

4.3.2 Compliance Statement

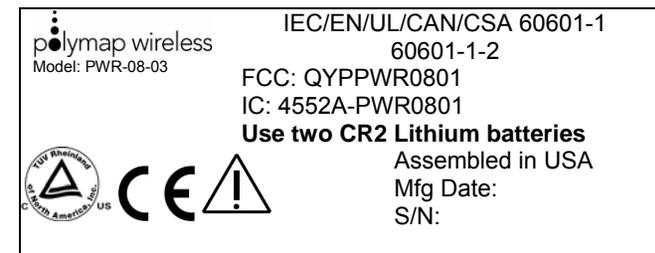
Polymap Wireless states that this device conforms to:

- FDA 21 CFR Parts 820
- IEC 60601-1: Medical Electrical Equipment – General Requirements for Safety
- IEC 60601-1-1: Medical Electrical Equipment – Collateral standard: Safety requirements for medical electrical systems
- IEC 60601-1-2: Medical Electrical Equipment – Collateral standard: Electromagnetic compatibility for medical electrical systems
- IEC 60601-1-4: Medical Electrical Equipment – Collateral standard: Programmable medical electrical systems
- UL 60601: Medical Electrical Equipment, Part 1 – General Requirements for Safety
- CSA: Medical Electrical Equipment, Part 1: C22.2601 No. 601.1 – M9 – General Requirements for Safety

- The manufacturer of this device complied with the following requirements applicable at time of manufacture:
 - ISO 13485:2003
 - ISO 13485/8 under Canadian Medical Device Conformity Assessment System (CMDCAS)

4.4 About the label at the bottom of the GMA

The label on the side of your GMA shows the unique ID number (serial number) of your device as well as some other things you might need to know:



Label on the bottom of the GMA

Seal / Mark	Meaning
	Device was tested to comply with the U.S. and Canadian safety directives.
	Device was tested to comply with the CE MDD directive.
	You should read accompanying documents before use.
IEC/UL/CAN/CSA 60601-1 60601-1-2	Device complies with both the safety and the radio requirements of these respective standards.
FCC: QYPPWR0801	FCC listing number for the device.
IC: 4552A-PWR0801	Industry Canada listing number for the device
S/N: 0015B4000000	Unique serial number

5 Operator Maintenance

5.1 Periodic Maintenance

Check your GMA now and then to make sure it is working properly and nothing is damaged. Make sure the cord that connects from your GMA to the OneTouch Ultra device is not frayed or damaged.

If your GMA needs repair or is not working right, contact Polymap Wireless for service right away.

5.2 Cleaning your GMA

Although you should not need to clean your GMA very often, here is how to do it:

1. Unplug the GMA from the OneTouch Ultra and remove it from the mesh pocket.
2. Take a soft cloth and dampen it with water or a weak solution of household dishwashing liquid mixed with water. Wring out the cloth.
Warning: Do **not** use any sprays or put your GMA in any liquid. Sprays and liquids may penetrate and damage the unit.
3. Gently wipe the outside of the unit with the damp cloth.
4. Reconnect the GMA to the OneTouch Ultra (see page 11), and close the mesh pocket (see page 13).

6 Technical Specifications

6.1 Batteries

The GMA uses two CR2 Lithium cells (3V each).
Max. Power consumption: 1W.

A few things to remember:

- Only use CR2 Lithium batteries.
- Replace both batteries at the same time, preferably from the same manufacturer.

6.2 Temperatures

- Use your GMA in temperatures ranging from 10° to 40° Celsius (50° to 104° Fahrenheit).
- Store your GMA in temperatures ranging from -40° to +70° Celsius (-40° to 158° Fahrenheit).
- If you move your GMA from a cold location to a warm location, please allow it to come up to room temperature before using it.

6.3 Compatibility with other electrical medical equipment

Like other electrical medical equipment, the GMA unit requires special precautions to make sure that it works with other electrical medical devices. This is called electromagnetic compatibility (EMC). As long as you install and use your GMA as noted in this manual, you should be fine.

NOTE: The GMA device has been tested to comply with IEC 60601-1-2:2001 requirements for EMC with other devices.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:
 (1) This device may not cause harmful interference, and
 (2) This device must accept any interference received, including interference that may cause undesired operation.

6.4 System Availability

If you end up needing to take a second reading shortly after a first reading, it is probably easiest to wait until the **PC** indicator has turned off.

There is no problem with taking several readings while out of range of the receiving station. The stored readings will all be sent the next time you take a new reading within range of the receiving station.

7 Trademarks

- Bluetooth® word mark and logos are owned by the Bluetooth SIG, Inc.
- Polytel® is a registered trademark of Polymap Wireless LLC.
- This product was designed solely by Polymap Wireless, independent of LifeScan™, makers of the OneTouch Ultra.

8 Index

- access points
 - changing, 20
 - defined, 6
- availability, 29
- batteries, 9
- blinking light, 7
- cleaning, 27
- compliance, 23
- connecting, 12
- devices
 - cleaning, 27
 - connecting, 12
 - disconnecting, 19
 - sharing, 22
 - troubleshooting, 21
 - using, 15
- disconnecting, 19
- electrical safety, 23
- electromagnetic compatibility, 28
- EMC, 28
- indicator light, 7
- installing, 12
- intended use, 6
- legal compliance, 23
- light indicator, 7
- major parts, 7
- other devices, 14
- PC on OneTouch, 16
- receiving station. *See* access points
- regulatory compliance, 23
- replacing batteries, 9
- retries, 18
- safety
 - electrical, 23
- setting up, 12
- sharing devices, 22
- temperatures, 28
- trademarks, 29
- traveling, 20
- troubleshooting, 21
- using devices, 15