

**Polytel® GMA
Glucose Meter Accessory for
Bayer Ascensia® Contour®
Model PWR-08-07**

USER MANUAL

Version: B

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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 PREPARING THE CARRYING CASE 11

3.3 CONNECTING THE DEVICES 13

3.4 PLACEMENT OF THE GMA AND RECEIVING STATION. 14

3.5 HOW TO USE YOUR GMA..... 15

3.6 IF THE TRANSMISSION DIDN'T SEND 18

3.7 DISCONNECTED GLUCOSE METER..... 19

3.8 WHEN YOU'RE TRAVELING..... 19

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

3.9 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 TEMPERATURES.....27
 6.3 COMPATIBILITY WITH OTHER ELECTRICAL MEDICAL
 EQUIPMENT.....27
 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 Contour glucose meter wirelessly to a receiving station. This GMA is designed for the Bayer Ascensia® Contour® glucose meter.

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 Contour® glucose meter.

The GMA receives the reading from the meter 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 your Contour meter 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 glucose meter
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. 9.)
Slow blinking	1 blink per 10 seconds	Last attempt to send data unsuccessful, waiting to retry.
Off	n/a	Either: Successfully sent data. or: Data not successfully sent, will send with next reading. (See p. 18.)

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:

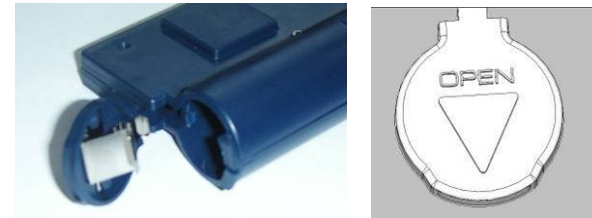


Figure 2: Battery lid. Slide lid in direction of arrow and allow it to swing open

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. 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 Preparing the carrying case

The meter has a hole in the side for the GMA connector, but the part of the case that holds it covers the hole, so we need to prepare the case first.

- 1) Prepare the carrying case. The meter has a hole on the right side:



Place the meter in its case, and mark the plastic covering the hole.

- 2) Take out the meter.
- 3) Cut a small hole in the plastic around the marked point (see figure below)



- 4) Cut a small slit (no more than 1/4" in the mesh near the point shown by the arrow.



Figure 4: modifications to the carrying case

3.3 Connecting the devices

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

- 1) Insert the glucose meter
- 2) Insert the GMA into the zippered pouch



Figure 5: glucose meter in 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.

4) Plug the cable from the GMA into the side of the glucose meter and press firmly into place. Make sure that the clear plastic is not pinched (this could prevent the cable from going in correctly).



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

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

3.4 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.

3.5 How to use your GMA

1. Insert the glucose test strip into the glucose meter and take your reading as you normally would. Instructions on using your Contour® meter should have come with the original box.
2. Remove the test strip as usual.
3. After you remove the test strip:
 - a. Press the “M” button on the meter
 - b. The Contour® meter displays “---“ on the screen, then some numbers, and “---“ again. This shows that it is sending the reading to the GMA.



Figure 6 “---“ shows on the glucose meter 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 7: Blinking light usually means your information is being sent. Please be patient.



IMPORTANT: If glucose meter screen does **not** show “---” or the red light does **not** come on shortly after taking a new reading:

Check that the GMA cable is firmly plugged into the glucose meter.
Try replacing both batteries (see page 9).

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 “---” disappears from the glucose meter.

3.6 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. Press the “M” button on the meter
You will see the “---” come on, as during a normal transmission

3.7 Disconnected glucose meter

Any readings taken when the GMA is not connected to the glucose meter 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.

3.8 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 access point.

Please speak with your monitoring service to set this up.

3.8.1 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.

3.9 Troubleshooting

What's Wrong?	What Caused It?	What To Do
Red light doesn't come on	Weak/missing batteries	Replace batteries (see p. 9).
	Disconnected cable	Plug cable firmly into glucose meter (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.
“---“ does not show on meter	Weak/missing batteries	Replace batteries (see p. 9).
	Disconnected cable	Plug cable firmly into glucose meter (see p. 12).
	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 glucose meter 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 Contour® 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 Contour® meters are approved for use by their manufacturer. Polymap Wireless is not responsible for their diagnostic accuracy or their 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:



Figure 8: 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: R47F2M03GL	FCC listing number for the device.
IC: 8229A-F2M03GL	Industry Canada listing number for the device
S/N: 0015B4010204	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 glucose meter 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 glucose meter 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 glucose meter (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 “---“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 Bayer, maker of the Ascentia[®] Contour[®] glucose meter.

8 Index

- access points
 - changing, 19
 - defined, 5
- availability, 28
- batteries, 8, 9
- blinking light, 6, 7
- Carrying case,
 - modifying, 11, 12
- Case, preparing, 11, 12
- cleaning, 26
- compliance, 22, 23
- connecting, 13
- devices
 - cleaning, 26
 - connecting, 13
 - disconnecting, 19
 - sharing, 21
 - troubleshooting, 20
 - using, 15
- disconnecting, 19
- electrical safety, 22
- electromagnetic
 - compatibility, 27
- EMC, 27
- indicator light, 6, 7
- installing, 13
- intended use, 5
- legal compliance, 22, 23
- light indicator, 6, 7
- major parts, 6
- Meter carrying case,
 - 11, 12
- other devices, 14
- receiving station. See
 - access points
- regulatory
 - compliance, 22, 23
- repair, 26
- replacing batteries, 8, 9
- retries, 18
- safety
 - electrical, 22
- service, 26
- setting up, 13
- sharing devices, 21
- temperatures, 27
- trademarks, 28
- traveling, 19
- troubleshooting, 20
- using devices, 15