Polytel® GMA2™
Glucose Meter Accessory
Model PWR-09-02

USER MANUAL
Version: 3

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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 glucose meter wirelessly to a receiving station.

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 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 LifeScan 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.

1.3 Configurations

The GMA is available in three different configurations, which determine which glucose meters are supported. Configurations are selected by inserting the proper cable into the GMA: **Cable must be firmly inserted until flush.**

- GMA2-L for LifeScan meters using “L” cable:

OneTouch® Ultra®
OneTouch® Ultra2®
OneTouch® UltraMini®
OneTouch® UltraEasy®
OneTouch® Select™
OneTouch® Basic™

- GMA2-B for Bayer meters using “B” cable:

Contour®
Contour® TS
Contour® XT
Contour® NEXT
Breeze2®

- GMA2-A for Abbott meters using “A” cable:

FreeStyle® Lite
FreeStyle® Freedom® Lite

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 indicator light on 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 Visual indicators

The GMA has small blue and red indicator lights in the pushbutton that blink in different patterns when it is doing different things.

Figure 1: Indicator light indicates status of the GMA. It may appear as blue or red, depending (see next page).

Here are the possible light patterns and their meanings:

Light looks like	Speed/Length	It means...
Blue on (no blinking)	Up to 60 seconds	GMA is getting data from glucose meter
Blue blinking	1 blink per second	GMA connecting to receiver. Please wait.
Blue, very fast blinking	2 blinks per second for 1-2 seconds	GMA sending data to receiving station
Blue, Slow blinking	1 blink per 10 seconds	Last transmit attempt did not work, waiting to retry
Red, blinking	1 blink per second	Data not successfully sent, will send with next reading (see page 19)
Red, very fast blinking	2 blinks per second for 10+ seconds	Replace batteries (see page 10)
Off	N/A	Successfully sent data

2.2 Battery Compartment

You can open the battery compartment by sliding the lid on the bottom open with your thumb.

Figure 2: battery lid

2.3 Size of your GMA

4.25 inches x 1.1 inches x 0.62 inches (108mm x 28mm x 16mm)

3 Operating Instructions

3.1 Changing the batteries

The GMA uses two alkaline AAA batteries that should last a couple of months.

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 (see figure 2)

Figure 3: Batteries should go in like this

2. Insert the batteries as shown in Figure 3.

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

3. Close the battery compartment by sliding it back into place.
4. If the red light still flashes for 10 seconds or longer, repeat steps 1 through 3 and:

- Check that you inserted the batteries in the right direction.
- Try replacing with a different pair of AAA size

batteries.

If you are still having trouble, see the “Troubleshooting” section on page 19.

3.2 Connecting the devices

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

1. Slide the meter into the carrying case:.
2. Place the GMA in the carrying case. Many different cases are provided by the manufacturers, so details will vary.

Ultra2

Polytel® GMA2

Contour next EZ

FreeStyle Lite

3. Plug the cable from the GMA into glucose meter and press firmly into place.

NOTE: Connect the GMA ONLY to the meters approved for your configuration Connecting it to any other device may make your readings inaccurate or damage one or both devices

NOTE: Due to a recent Bayer decision, Contour XT meters with serial numbers above 6000001 and Contour Next EZ meters with serial numbers above A000001 require the GMA to be unplugged from the meter during measurements.

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 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 9 to learn more about the indicator light.

3.4 Pairing

In most cases, Bluetooth pairing is initiated automatically by the GMA. Receiving station should be pairable. For HDP use, you can make the GMA pairable by pressing the button three times, making the GMA light blink red at one-second intervals

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 glucose meter should have come with the original box.
2. Remove the test strip as usual.
3. After you remove the test strip:

- The blue light on the GMA turns on automatically.
- The meter will show activity:

- LifeScan meters display 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.

- Bayer meters show the number of measurements counting down. The display will stay on for two minutes. This is normal.
- Abbott meters show all the display elemets active (nothing readable).**Figure 4: PC shows on the glucose meter when the GMA is receiving your readings**

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

NOTE:
Some meters automatically wake up the GMA. For those that do not, please see chart below:

Meter	GMA	How to send
OneTouch Ultra	Automatic	
OneTouch Ultra2 versions A & B	Automatic	
OneTouch Ultra2 newer versions	Manual	Press the button on the GMA
OneTouch Ultra Mini/Easy	Automatic	
OneTouch Select /Basic	Manual	Press the button on the GMA
Bayer Contour/ Breeze2	Some are automatic, some are manual	Press the “M” button on the meter itself
Abbott FreeStyle	Manual	Press the button on the GMA

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 glucose meter screen does not show PC or the light does not come on shortly after taking a new reading:

- Check that the GMA cable is firmly plugged into the glucose meter
- Try replacng both batteries (see page 10).
- 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 glucose meter.

3.6 If the data was not sent

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.

3.7 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.

3.8 Troubleshooting

What's wrong?	What caused it?	What to do
Blue light doesn't come on	Weak/missing batteries	Replace batteries (see p. 10)
	Disconnected cable	Plug cable firmly into glucose meter (see p. 14)
	GMA needs manual operation to start	Please see p. 17
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
No response on meter display	Weak/missing batteries	Replace batteries (see p. 10)
	Disconnected cable	Plug cable firmly into glucose meter (see p. 14)
	Damage 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.
NOTE! Disregarding the safety information provided is considered abnormal use

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 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.

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 I Medical Devices per 21CFR, and an In Vitro Diagnostic Device under the

provisions of the EU IVD Directive 98/79/EC. It is also a low power wireless device as defined in the EU Radio Equipment Directive 2014/53/EU

The various glucose meters are approved separately for use by their manufacturer. Polymap Wireless is not responsible for their diagnostic accuracy or their electrical safety.

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:

- Radio Equipment Directive 2014/53/EU

- In Vitro Diagnostic Medial Devices Directive 98/79/EC
- Restriction of the use of certain hazardous substances in electrical and electronic equipment 2011/65/EU

The following standards have been applied in its design and manufacture:

- EN 300 328 V1.7.1
- EN 301 489-1 V1.9.2
- EN 301 489-17 V2.2.1
- EN 61326-1: 2006
- EN ISO 13485:2012
- ISO 13485/8 under Canadian Medical Device Conformity Assessment System (CMDCAS)
- EN 50581:2012

• *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:

Seal/Mark	Meaning
CE	The device complies with all applicable EU directives that require the affixing of this mark.
	You should read accompanying documents before use.

Seal/Mark	Meaning
	Device uses Bluetooth 2.1
FCC: QYPPWR0902	FCC listing number for the device.
IC: 4552A-PWR0902	Industry Canada listing number for the device
S/N: 0015B4010204	Unique serial number
	Device is listed with Austrailian Comunications and Media Authority.
R-NZ	Device is listed with New Zealand authorities
Complies with IDA Standards N1569-15	Device is listed with Singapore authorities

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 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 glucose meter (see page 14), and close the mesh pocket.

6 Technical Specifications

6.1 Batteries

The GMA uses two AAA cells (1.5V each). Max. Power consumption: 0.5W.

6.2 Temperatures

- Use your GMA in temperatures ranging from 5º to 40º Celsius (41º to 104º Fahrenheit).
- Store your GMA in temperatures ranging from -40º to +70º Celsius (-40º to 158º 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.

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.

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

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 indicators on the meter have 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.
- Ultra®, Ultra2® and UltraMini® are registered trademarks of LifeScan, Inc.
- CONTOUR® , BREEZE®2 are registered trademarks of Bayer.
- FreeStyle® is a registered trademark of Abbott Diabetes Care.

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